UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* DONALD R. GALMINES	:	
	:	Civil Action No. 06-3213
BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, DELAWARE, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTES, MICHIGAN, NEVADA NEW HAMPSHIRE, NEW MEXICO, TENNESSEE, THE COMMONWEALTH OF VIRGINIA, AND THE DISTRICT OF COLUMBIA	:	Honorable Gene Pratter
Plaintiff and Relator	:	
v.	:	
NOVARTIS PHARMACEUTICALS CORPORATION,	:	
Defendant.	:	

RELATOR DONALD GALMINES'S MEMORANDUM IN OPPOSITION TO DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S MOTION TO DISMISS RELATOR'S COMPLAINT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES **PAGE**

STATUTES

REGULATIONS

OTHER AUTHORITIES

INDEX OF EXHIBITS

INTRODUCTION

Donald Galmines worked for defendant Novartis Pharmaceuticals from 2001 until early 2006 as a marketing representative selling, primarily, an eczema cream brand-named Elidel. The active ingredient in Elidel, pimecrolimus, is of a class of drugs called "topical calcineurin inhibitors," or immunomodulators. Their purpose is to suppress the immune system at the site of an eczema flare. However, they may also have potentially-serious side effects, from slowing recovery from infections to certain types of cancer. When Novartis asked the FDA to approve Elidel for human use, the FDA responded with a narrowly-tailored label: Elidel is approved for use only for patients older than two years, for whom first-line treatments (usually, topical corticosteroid creams) prove ineffective or unwise, and only for short-term relief of the symptoms of atopic dermatitis (eczema).

In this *qui tam* case brought under the False Claims Act, 31 U.S.C. § 3729, *et. seq*., Mr. Galmines alleges that despite the careful and narrow labeling allowed by the FDA, Novartis, for months before Elidel was even on the market, prepared him and his colleagues to urge physicians to prescribe Elidel for use on any infant older than 90 days, for extended periods, and as a first-line preparation. This marketing plan was effectuated with shocking calculation and callousness: Physicians were lied to about whether the FDA found Elidel to be safe for infants (it did not; in fact, it found serious safety problems); lied to about whether Elidel posed a cancer risk (animal studies showed that it does; the jury is still out on humans); and paid a sultry mix of payments to encourage their overprescribing of Elidel. Doctors were given trips, speaking engagements, meals, and paid to allow Novartis personnel to follow them around their offices for a few hours, a practice called "preceptorships."

The result was that a huge number of Elidel prescriptions were written for children under the age of two. The result of *this* was that the FDA convened a —Pediatric Advisory Panel" to examine whether Elidel and a related drug should be the subject of specific warnings against use on children. At that panel's hearings, senior Novartis personnel specifically advised the panel that they strictly guarded against off-label marketing, even as Mr. Galmines and his colleagues were trained, retrained, and directed to market Elidel for use on infants and other off-label purposes. These facts, Mr. Galmines reports in copious detail.

In this case, Mr. Galmines alleges that Novartis caused extensive violations of the False Claims Act because its off-label marketing and kickback campaign caused submission to the United States of claims for payment for unallowable uses of Elidel. This is not a novel theory to Novartis, which late last year pled guilty to selling misbranded pharmaceuticals for its off-label marketing of Trileptal, paying more than $400 million in civil and criminal sanctions. The case is now before the Court on Novartis' motion to dismiss, which attacks the complaint on jurisdictional and other grounds. We show in this memorandum that Novartis' motion to dismiss should be denied in all particulars.

SUMMARY OF THE ARGUMENTS

Novartis asserts that the complaint in this case is barred by the False Claims Act's —first to file" provision because two former Novartis employees filed a *qui tam* case against Novartis in Michigan in 2005. In that case, however, the district court, Judge Anna Diggs Taylor presiding, found that the court lacked jurisdiction over the relators' complaint because there had been public disclosures and they did not qualify as original sources under the False Claims Act. Judge Taylor also found that the complaint did not satisfy the particularity requirement of Rule 9(b), Fed. R. Civ. P. Several courts have held, and the Department of Justice agrees, that a

placeholder *qui tam* complaint which is insufficient to satisfy Rule 9(b) cannot constitute a —first filed" case for purposes of the first-to-file bar. Here, the insufficiencies of the Michigan complaint are patent: There is no indication of any of the who, what, where, when or why required by Rule 9(b); in fact, there is no concrete evidence that any doctor was actually subjected to off-label marketing at all.

The Third Circuit has squarely acknowledged the importance of Rule (9)(b) analysis in the parsing of allegations under the first-to-file provision to meet the —golden mean" between knowledgeable whistleblowers and those who are not. Simply put, Mr. Galmines is; the Michigan relators were not. The first-to-file challenge fails.

Novartis also goes to elaborate lengths to show that its shocking campaign to market the use of a potential carcinogen on the skin of infants despite the FDA's direct prohibition that was in the public domain. Indeed, in 2005-06, the FDA held hearings which resulted in the imposition of a —boxed warning" or —Black Box" on the Elidel label, specifically warning against its use on children under two because of questions surrounding the cancer risk. On the other hand, there was nothing in the public domain about the nature and extent of Novartis' off-label tactics: Mr. Galmines alone has brought that information forward.

Relator recognizes that there was sufficient smoke around the marketing of Elidel for use on infants and other off-label purposes to warrant a finding by the Court of statutorily-significant public disclosures. The question becomes, then, whether Mr. Galmines qualifies as an original source—the other —golden mean" inquiry. There is no question that he has direct and independent knowledge of his allegations; Novartis does not seriously contend otherwise. They do contend that he was required to tell the government before anybody reported anything in the press, a contention another member of this Court long ago rejected and which has been rejected

by many others; and that the complaint is not sufficiently technical in its jurisdictional allegations. Relator respectfully asks that the Court reject these contentions, as they are makeweight.

Novartis also makes myriad arguments for dismissal asserting that Mr. Galmines' complaint fails to comport with Rules 12(b)(6) and 9(b), Fed. R. Civ. P. However, none of Novartis' arguments are novel. Rather, courts from coast to coast have rejected each and all of them. Accordingly, the motion before the Court should be denied.

Mr. Galmines has stated a claim under Rule 12(b)(6). The reason for Novartis' liability is straightforward. Novartis is not allowed to market Elidel for off-label uses nor provide kickbacks to physicians to induce prescriptions for such uses; and federally funded healthcare programs will not reimburse prescriptions caused by off-label marketing or tainted by kickbacks. In spite of clear statutory prohibitions, Novartis engaged in a long-term scheme to increase its sales of Elidel for off-label purposes. As a result, physicians wrote many thousands or more off-label prescriptions were submitted to federally funded health care programs by pharmacists.

As to the Rule 9(b) issues, Mr. Galmines' detailed and concise allegations provide Novartis with ample notice of the specific fraud allegations it faces. The Complaint provides intricate detail regarding the methods and means of Novartis' off-label marketing and kickback schemes and provides detailed evidence of the success of these schemes.

In sum, Mr. Galmines has satisfied the Federal Rules of Civil Procedure requirements of a pleading. The Complaint overwhelmingly states claims upon which relief may be granted and Mr. Galmines should be permitted to proceed with his case.

FACTUAL BACKGROUND

A. The FDA's limited approval of Elidel for atopic dermatitis

By some estimates, 35 million Americans suffer from atopic dermatitis, a form of eczema characterized by inflammation of the skin caused by the release of cytokines and manifesting in skin lesions (or —flares") caused by bacteria interacting with the atopic dermatitis. Compl. ¶ 25, 27, 30. Most of them develop lesions in infancy; 65% during their first year of life, and 90% before the age of five. Compl. ¶ 26. Novartis developed Elidel (pimecrolimus 1% in cream suspension) in response to the increasing numbers of children diagnosed with atopic dermatitis, as well as to the real and perceived side-effect of topical corticosteroid treatment. Compl. ¶ 29. Pimecrolimus, Elidel's active ingredient, is a topical immunomodulator—a class of drug that suppresses T cell and mast cell activation which in turn inhibits inflammatory cytokine release that triggers atopic dermatitis. Compl. ¶ 30.

FDA approval is a precondition to the marketing of a drug sold in the United States. FDA approval also is a precondition for prescription reimbursement by any federally- funded health care program, to include Medicaid and Medicare. Compl. ¶ 33.

Drug manufacturers seek FDA approval by submitting a —New Drug Application" to the agency. In December of 2000, Novartis submitted a New Drug Application seeking approval of Elidel for treatment of atopic dermatitis in patients older than three months. Given the high percentage of eczema sufferers whose symptoms develop in infancy, Novartis' reason for seeking approval for infant use is easily divined. However, the results of Novartis' human trials of Elidel had resulted in seriously-incomplete data for both safety and efficacy of its new drug when used on infants. Compl. ¶¶ 31, 34-36.

The FDA granted marketing approval for Elidel in December 2001. Compl. ¶ 49. However, based on its year-long review process, the FDA identified substantial evidence that

Elidel was not proven safe for use in infants. The FDA therefore granted Novartis the right to market Elidel only for use in patients older than 24 months. Compl. ¶¶ 35, 46-49. The FDA also limited the use of Elidel for –second line" therapy; that is, Elidel was approved to be prescribed only when approved first –line treatment (usually, treatment with emollients or with topical cortisone creams) was ineffective or contraindicated. Compl. ¶¶ 28, 49.

The FDA's findings that Elidel was not safe for use on infants centered on clinical evidence —that infants have a significant increase in infection such that in this reviewer's opinion warrant that ASM 1% cream not be used in this [0-23 month] age group for atopic dermatitis." Compl. ¶ 44. The adverse events identified in the FDA Medical Review included, among numerous others, upper respiratory tract infection; nasopharyngitis; otitis media; gastroenteritis; viral upper respiratory infection; pyrexia; teething; diarrhea; and restlessness. Compl. ¶¶ 45-46.

The FDA was also concerned about potential cancers caused by Elidel. Pimecrolimus, the active ingredient in Elidel, is an immunosuppressant; that is, it suppresses the immune response. One result of immunosuppression can be the formation of tumors, and studies of pimecrolimus revealed cases of lymphadenopathy (lymph node swelling) and high rates of malignancies and neoplastic lesions. Compl. ¶¶ 38-40, 44, 46. Moreover, the FDA specifically found that in both short- and long-term, double-blind and open-label clinical testing, Elidel exhibited a —poor safetyprofile in infants," showing a statistically significant increase in a variety of negative side effects as compared to the use of placebos. Compl. ¶¶ 41-46, 48-50. To be precise,

> subjects in the ASM 1% arm continue to have a greater incidence of adverse events including nasopharyngitis, URIs, otitis media, pyrexia, bronchitis, tonsillitis, influenza, teething, cough, irritability, chickenpox, vomiting, rhinitis, asthma, dermatitis contact, and conjunctivitis. [The data] also demonstrates that there are adverse events that are now statistically significant in their occurrence in infants on ASM 1% cream after use over a 6 months period as compared to

> vehicle [placebo] that were not present in the short-term 6 week vehicle controlled trial. These include viral rash (4.4% vs. 0), lower respiratory tract infection [pneumonia (3.9% vs. 0)], eye infection (2.5% vs. 0), pharyngitis 5 (2.5% vs. 0), respiratory tract infection NOS (2.5% vs. 0), toothache (2.9% vs. 0), rhinorrhea (3.9% vs. 0), wheezing (3.9% vs. 0), hypersensitivity (8.3% vs. 2.2%), and irritability (2.5% vs. 0).

Id. at ¶ 45.

B. Novartis' off-label marketing campaign and kickback scheme

Despite knowing that it was illegal for it to market Elidel for any non-approved indication, Novartis engaged in an aggressive national campaign to convince pediatricians to prescribe Elidel for use on infants exhibiting early signs of eczema. Compl. ¶¶ 51-54, 92. Novartis created and trained its sales representatives to disseminate misleading messages promoting the off-label use specifically for infants under two years of age; as a first-line treatment; and for chronic/long-term use. Compl. ¶ 54. Novartis marketed a variety of materials directly to physicians to promote these off-label uses including numerous visual aids promoting Elidel for first-line and long-term treatment as well as information from Novartis -sponsored articles promoting Elidel for infants included in reprints, press releases, and detail pieces. Compl. ¶¶ 60-64, 72-75, 76, 82-83. All these materials omit information regarding the increased adverse side effects and cancer risk associated with infant and long term Elidel use. *Id.* Sales representatives were also trained to falsely imply that the FDA had allowed it to retain infant study data in the labeling information because Elidel was safe for use in infants. Compl. ¶¶ 47-48, 58-59, 65, 77.

Novartis instructed its sales force that its goal was for Elidel to —replace all mid-level steroid usage[.]" Compl. ¶ 56. To this end, Novartis built its sales pitch around —topical corticosteroid phobia" and trained sales representatives to falsely assert that Elidel was the safer alternative despite the utter lack of data comparing the safety and efficacy of Elidel to topical

corticosteroids (which have been found safe and effective for first-line use by the FDA). Compl. ¶¶ 49, 57, 68, 78, 88, 99.

In addition to direct to physician marketing, these off-label messages were promoted by Novartis and Novartis' paid physician speakers during Continuing Medical Education seminars. Compl. ¶¶ 118, 121-122. These off-label messages were also promoted directly to the public through Novartis' website. Compl. ¶¶ 73, 99-100.

In conjunction with its off-label marketing campaign, Novartis engaged in the provision of systemic kickbacks to induce physicians to write off-label prescriptions for Elidel. Compl. ¶¶ 2, 128, 142, 150-152. These kickbacks included fine dining, wine, and prepaid travel arrangements. Compl. ¶¶ 118-119, 134-139. Novartis also provided physicians with honoraria, preceptorships and speaking engagements, which were not linked to fair market value of any service the physician provided, but simply a means to funnel money to physicians for writing Elidel prescriptions. Compl. ¶¶ 120, 123-125. In fact, many of the speaking engagements for which physicians were paid never occurred. Compl. ¶¶ 128-131, 140-141. Novartis especially targeted high prescribing physicians for kickbacks as a way to encourage further prescriptions of Elidel. Compl. ¶¶ 117,123-124, 133,

Novartis' off-label campaign and kickback schemes were immensely successful, and its Elidel sales skyrocketed from 2001 to 2004. Comp. ¶¶ 106-108. Novartis itself attributed 20% of sales to off-label infant use alone, and the FDA attributed at least 14% (approximately 1.2 million prescriptions) of Elidel sales to this use. Compl. ¶¶ 106, 116.

C. The FDA Black Box label Change

The explosive rise in Elidel sales for use on infants, along with increasing concerns about Elidel's cancer risk due to evidence of "systemic absorption and systemic effect with potential for serious and long-term complications," caused the FDA to re-examine the approved label in

2005. Compl. ¶¶ 102-103. In February 2005, the FDA Advisory Committee held a hearing regarding the safety of Elidel for children, and in particular to address the potential cancer risk from Elidel use. Compl. ¶¶ 103-104. Excerpts from the hearing are included at Exhibit 1. The panel discussed the critical problem of "wide-scale" Elidel use "outside the package insert" for both children and as a first-line treatment for atopic dermatitis. Compl. ¶¶ 105-106. Despite the overwhelming numbers of Elidel prescriptions for infant use, Novartis' Elidel Medical Director, Dr. Carle Paul, stated that Novartis did not engage in off-label marketing of Elidel. Compl. ¶ 109-110. Exhibit 1 at tr. p. 169.

The result of this and follow-on hearings was the addition to the Elidel label of a Black Box warning – the most serious of five levels of warning that the FDA can require on a label, indicating a potential for serious or life-threatening side-effects. Compl. ¶ 111.[1] The boxed warning specifically advises physicians, that Elidel is approved for: only short-term and intermittent eczema use; that Elidel should be used only as a second-line of treatment; Elidel is not approved for use in children under two years of age and that Elidel showed significant adverse side-effects in clinical trials; all persons with weakened immune systems should not use Elidel; and that animal studies showed an increased risk of cancer with increased exposure to Elidel. Compl. ¶ 112.

Novartis' cynical and illegal marketing campaign continued even after the FDA proposed including a Black Box warning on Elidel's label. In spring of 2005, Novartis instructed its sales representatives at a national sales meeting to continue to promote Elidel use for infants. Compl. ¶ 95. In 2006, Mr. Galmines was reprimanded by his supervisor for failing to keep unapproved

[1] For reasons unknown, Novartis includes only the 2001 Elidel labeling information. For the court's complete record, we include at Exhibit 2 the 2006 label as revised after the FDA Advisory Committee hearings.

reprints promoting Elidel use for infants with him and for telling a physician he should not write prescriptions for infants. Compl. ¶ 96.

ARGUMENT

I. THIS ACTION IS NOT BARRED BY THE FALSE CLAIMS ACT'S FIRST-TO-FILE PROVISION

Novartis urges the Court to dismiss Mr. Galmines' complaint pursuant to 31 U.S.C. § 3730(b)(5), which provides:

> When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

Novartis asserts that this case is "a related action based on the facts underlying" a putative *qui tam* case, *United States ex rel. Moyer and Shelton v. Novartis Pharmaceutical Corp*., No. 05-72242 (E.D. Mich., complaint filed June 7, 2005).

However, that case made no allegation related to illegal off-label marketing for use in infants, and no allegations relating to illegal marketing for first-line use of Elidel. Moreover, the district court found that it lacked subject-matter jurisdiction over the *Moyer-Shelton* case, and also found that the complaint in that case failed to satisfy the specificity requirements of Rule 9(b), Fed. R. Civ. P.

We show in the paragraphs which follow that the *Moyer-Shelton* case was, as to allegations concerning Elidel, a *qui tam* cipher, wholly insufficient to bar this case.

A. The first-to-file provision comes into play only when the second complaint is based on the same material facts as the first filed

The first-to-file provision was designed by Congress to address the risk that the government might have to pay multiple relators' shares for the same behavior. *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc*., 149 F.3d 227, 233-34 (3d Cir. 1998).

"The first-to-file rule furthers the policy of the FCA in that '[t]he first-filed claim provides the government notice of the essential facts of an alleged fraud, while the first-to-file bar stops repetitive claims.'" *In re Pharm. Indus. Average Wholesale Price Litig*., 2008 U.S. Dist. LEXIS 53862 at *2 (D. Mass. July 15, 2008)(quoting *United States ex rel. Lujan v. Hughes Aircraft Co*., 243 F.3d 1181, 1187 (9th Cir. 2001)). The Third Circuit has long recognized, however, that

> [T]he 1986 amendment [to the False Claims Act], which introduced the current version of section 3730(b)(5), sought to achieve "the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." In construing section 3730, we are mindful of the need to preserve a balance between the amendment's two competing goals.

LaCorte, 149 F.3d at 234 (quoting *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 649-50 (D.C. Cir. 1994)). Simply put, "[c]onstruing § 3730(b)(5) to create an absolute bar would permit opportunistic plaintiffs with no inside information to displace actual insiders with knowledge of the fraud." *United States ex rel. Campbell v. Redding Medical Center*, 421 F.3d 817, 824 (9th Cir. 2005).

Predictable application of the first-to-file bar is also important to the institutional interests of the United States. The government's right of action against a False Claims Act target is limited to three years from when the Department of Justice becomes aware of "facts material to the right of action." 31 U.S.C. § 3731(b)(2). Thus, if this case is dismissed—even if that dismissal were without prejudice to the government's rights—the federal and state governments could be foreclosed from pursuing the off-label allegations and kickback allegations brought by Mr. Galmines. The Third Circuit recognized in *LaCorte* that "duplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." 149 F.3d at

234. But the central words here are "essential facts of a fraudulent scheme," and that necessarily means more than that someone has claimed, with no material detail, that a defendant has violated the False Claims Act.

Thus, while Novartis may wish to argue that the *Moyer-Shelton* complaint put the United States on notice of the False Claims Act schemes identified in the complaint in this case, Relator respectfully submits that such an argument would not be credible. The government's lawyers, confronted with a *qui tam* complaint, are "not like pigs, hunting for truffles buried in [*qui tam* complaints]." *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991) (*per curiam*). The proposition that large pharmaceutical companies engage in off-label marketing and pay kickbacks to high prescribers has for many years not been novel. But the suggestion that the *Moyer-Shelton* complaint, which made the briefest hearsay allegations regarding Elidel, put the Department of Justice on notice of the copiously-described facts based on personal knowledge alleged in Mr. Galmines' complaint does not withstand scrutiny. The search the Third Circuit has mandated is for the golden mean—not the least common denominator.

B. The first-to-file provision only applies where there was jurisdiction over the earlier complaint, and where that complaint satisfied Rule 9(b)'s particularity requirements

The Third Circuit's *LaCorte* decision has substantially framed judicial discussion of the first-to-file provision since its publication 13 years ago. Its primary import is its analysis of the statutory phrase "based on the facts underlying the pending action." In *LaCorte*, a half-dozen relators brought suit against a laboratory-services company, alleging a variety of frauds. The first three cases were consolidated and litigated together, and the three which were filed later were dismissed under the first-to-file provision. 149 F.3d at 232.

In affirming dismissal of the later-filed cases, the court of appeals first noted that under the plain language of the statue, —[i]a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details." *Id*. at 232-33. This language led the First Circuit, in a situation quite similar to this, to reject the contention that a well-detailed complaint filed after a vague or overly-general complaint runs afoul of the first-to-file provision. In *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 33 (1st Cir. 2009), *cert. denied* 130 S.Ct. 3454 (2010), the court held that a first-filed complaint which made a general, two-paragraph allegation that a drug had been marketed off-label did not preclude a second-filed complaint which included specific marketing activity in furtherance of the off-label scheme. In prose which is, as we show below, highly relevant here, the *Duxbury* panel said:

> As this allegation fails to encompass the other allegations contained in the [second-filed] Blair Complaint concerning OBP's _off-label' promotion, it fails to allege the "essential facts" of the _off-label' promotion scheme contained in the Blair Complaint. In fact, the Original [first-filed] Complaint nowhere refers to an _off-label' promotion scheme. Thus, we conclude that the Original Complaint cannot trump the Blair Complaint for purposes of the _first-to-file' rule.

Id. at 33. *LaCorte* controls here, of course, and its central holding—that the first-to-file provision has effect only where there is identity between the central ***facts*** of the two complaints—obviously will guide this Court's analysis of Novartis' motion.

The *LaCorte* panel rejected the relators' argument that —unless section 3730(b)(5) is limited to suits alleging identical facts, any relator who discovers a false claim will simply plead a very broad cause of action so as to preempt claims by later plaintiffs." 149 F.3d at 234. In holding that the use of broadly-pled placeholder complaints would pre-empt cases brought by knowledgeable relators, the court said:

> We do not believe that the decision we reach today creates an undue risk that plaintiffs will engage in such artful pleading. *Federal Rule of Civil Procedure 9(b) requires plaintiffs to plead fraud with particularity, specifying the time, place and substance of the defendant's alleged conduct. This requirement provides sufficient deterrence against overly broad allegations.*

Id. (emphasis supplied). Thus, as the Third Circuit's seminal holding demonstrates, there is —[o]ne important caveat to this first-to-file rule":

> in order to preclude later-filed qui tam actions, the allegedly first-filed qui tam complaint must not itself be jurisdictionally or otherwise barred. …Indeed, if the first complaint is either jurisdictionally precluded, see 31 U.S.C. § 3730(e), **or legally incapable of serving as a complaint, see Fed. R. Civ. P. 9(b))**; …then it does not properly qualify as a —pending action" brought under [the] FCA, 31 U.S.C. § 3730(b)(5).

United States ex rel. Poteet v. Lemke, 604 F. Supp. 2d 313, 323 (D. Mass. 2009)(quoting *United States ex rel. Poteet v. Medtronic, Inc*., 552 F.3d 503, 516 (6th Cir. 2009))(emphasis supplied). The Ninth Circuit relied on *LaCorte* in *Campbell*, 421 F.3d at 821, finding that —an overly broad interpretation of the first-to-file bar, allowing even sham complaints to preclude subsequent meritorious complaints in a public disclosure case, would contravene" Congress's intent —in enacting the 1986 amendments to the FCA" to —provide incentives to qui tam whistleblowers to come forward". And the Sixth Circuit relied on *LaCorte* in *United States ex rel. Walburn v. Lockheed Martin Corp*., 431 F.3d 966, 972-73 (6th Cir. 2005). In that case, two relators individually sued Lockheed in connection with its performance under a government contract to manage an Ohio nuclear facility. The second-filed complaint (that of Mr. Walburn) was dismissed under the first-to-file provision. Citing *LaCorte*, the court of appeals found that holding to be erroneous because the first-filed complaint was too general to satisfy the specificity requirement of Rule 9(b). It was also insufficient to put the government on notice of the specific fraud alleged by Walburn, and the first-to-file provision did not apply:

> A complaint that fails to provide adequate notice to a defendant can hardly be said to have given the government notice of the essential facts of a fraudulent scheme, and therefore would not enable the government to uncover related frauds.

Id. at 973 (citing *LaCorte*, 149 F.3d at 234).

Given the prominence of *LaCorte* in this context, it is not surprising that the United States—which has by far the most skin in the game of False Claims Act interpretation—has squarely endorsed the *LaCorte-Walburn* principle that a bare-bones, first-filed complaint which does not meet Rule 9(b)'s particularity requirements can preclude a later, well-pled complaint. In *United States ex rel. Batiste v. SLM Corp*., 740 F. Supp.2d 98 (D.D.C. 2010), *app. pending*, the Department of Justice has filed a brief *amicus curiae* urging "that the Sixth Circuit's premise, that an FCA complaint must satisfy Rule 9(b) to provide adequate notice of the alleged fraud to both defendant and the Government, was correct." Exhibit 3 at 17. Relator respectfully urges this Court to consider closely the fact that the United States takes this position, because it indicates that it is more important to the Department and its client agencies that they receive *good information* than that they avoid paying a statutory share to a proper relator.

C. The *Moyer-Shelton* case did not trigger the first-to-file provision with respect to the allegations made in this case

Against this background, we review the "facts underlying" *Moyer-Shelton.* Based on the lack of factual similarity—much less identity—between the complaints, we will show that the *Moyer-Shelton* complaint does not trigger the first-to-file bar under the *LaCorte* standard. Then we demonstrate that, even if it did, because the district court lacked subject-matter jurisdiction over the *Moyer-Shelton* case, *and* that the *Moyer-Shelton* complaint failed to satisfy the particularity requirements of Rule 9(b), the Michigan case simply does not preclude this one.

1. The "facts underlying" *Moyer-Shelton*

The 10-page *Moyer-Shelton* complaint (three pages of which discuss retaliation claims), which was filed on June 7, 2005, is attached as Novartis Exhibit B. According to its scant allegations, relator Shelton worked for Novartis as a sales representative tasked with the sale of the antifungal product Lamisil and Elidel, and relator Moyer was her supervisor. They became aware of what they characterize as an

> illegal scheme to encourage physicians to prescribe Lamisil in a specific manner and with a specific scheme which would require the patient to make multiple trips to the physician's office and have multiple procedures performed which were unnecessary and unrelated to the efficacy of the drug.

Moyer-Shelton complaint, ¶ 9. The complaint focuses primarily on Lamisil. With respect to Elidel, the complaint alleges:

1. *"[t]he formation of a nationwide network of employees falsely referred to as medical liaisons'" whose job was to market Elidel to "health care insurers." Id., ¶ 12.a.*

   The paragraph makes no mention of federally-funded health insurance programs. Mr. Galmines' complaint in this case makes no mention of "medical liaisons."

2. *"The illegal direct solicitation of physicians and the encouragement of off-label use of Elidel for treatment of psoriasis and seborrhea" [sic.], and the "use [of] Elidel with occlusive dressings to increase its potency." Id., ¶ 12.b.*

   Mr. Galmines' complaint makes no allegation regarding the marketing of Elidel for treatment of psoriasis, nor does it make any allegation regarding "occlusive dressings." With respect to seborrhea, Mr. Galmines does allege that "[o]n or about January 18, 2002, Mr. Galmines was instructed by a Novartis Sales Trainer named Lisa, whose last name he does not recall, that Elidel should replace all mid-level steroid usage, including poison ivy, rosaceae, [and] seborrheic dermatitis.'" Compl. ¶ 56.

3. *"The making of false statements to physicians concerning ways to increase the potency of Elidel and the alternative off-label uses of the drug and/or the making of false statements regarding the relationship of the use of Elidel and the development of lymphoma." ¶ 12.c.*

> Mr. Galmines' complaint makes no allegations regarding "ways to increase the potency of Elidel." Nor does it make any allegations regarding "false statements regarding the relationship of the use of Elidel and the development of lymphoma."

4. *"The active training of Novartis employees in methods to avoid detection of their illegal activities by the FDA" including "gift certificates and other benefits for frequent prescribers." Id., ¶ 12.d. Later, the complaint alleges that Novartis paid kickbacks with respect to "Lamisil and/or Elidel" in the "form of cash payments, grants, gift certificates, entertainment and other benefits." Id., ¶ 15.*

   Mr. Galmines makes no allegation of even one actual kickback to an Elidel prescriber. He also alleges, with many specific examples, the payment of kickbacks, to include meals, trips, and speaking engagements, to Elidel high prescribers. *Id.* ¶¶ 117-143.

Perhaps most important, the *Moyer-Shelton* complaint makes no allegation that either Ms. Moyer or Ms. Shelton had any first-hand knowledge or experience with respect to Novartis' off-label marketing of Elidel. It identifies no particular off-label marketing practices or techniques which were *actually deployed* relating to Elidel, nor does it identify any Novartis personnel who advocated, engaged in, or knew about the claimed illegal off-label practices except to say that three representatives had a document which listed off-label uses of the drug *(Moyer-Shelton* compl. ¶ 22)—something which is, at base, not illegal at all.

Similarly, there is no indication of any actual knowledge, first-hand or second-hand, of the use of kickbacks to influence physician prescribing habits for Elidel; and with respect to the allegation that Novartis dispersed personnel to downplay the carcinogenic nature of Elidel in discussions with insurance companies (*Moyer-Shelton* compl. ¶ 12(a)), it is not so much as alleged that there was any nexus to federally-funded health insurance programs.

The United States declined to intervene in the *Moyer-Shelton* case. After Judge Taylor unsealed the complaint and the relators served it, Novartis moved to dismiss, asserting a lack of subject-matter jurisdiction due to alleged public disclosure of off-label marketing allegations

relating to Elidel, and separately asserting that Ms. Moyer and Ms. Shelton lacked sufficient information to satisfy Rule 9(b), Fed. R. Civ. P.[2]

In opposing Novartis' motions to dismiss, the relators attached as exhibits the pre-filing disclosures they made to the Department of Justice.[3] These pre-filing disclosures, which are in affidavit form, attached as Exhibits 6 (Moyer) and 7 (Shelton), constituted the "information on which the allegations are based" under the original source provision of the FCA, 31 U.S.C. § 3730(e)(4)(B). And with respect to Elidel, these documents demonstrate that neither Moyer nor Shelton had *any* information about actual illegal marketing of Elidel. The sum total of Ms. Moyer's allegations regarding Elidel is these, the last two paragraphs of her affidavit:

> 20. . . . I was also informed that Robert Budi instructed physicians at a Consultants' meeting how to use Elidel with occlusive dressings to increase potency, a clear contraindication.
>
> 21. I also know that after the reports of the complication of lymphoma associated with Elidel, Robert Budi's representatives took a medical liaison who could give grant money, to meet with Pharmacy Therapeutic Committees to convince them lymphoma was not a problem and Elidel should be on the formulary.

Exhibit 4, ¶¶ 20-21.

Although according to her affidavit, Ms. Shelton was tasked with the marketing of Elidel, her disclosure as relates to Elidel is even less substantive than Ms. Moyer's:

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[2] Novartis filed separate motions to dismiss. These are attached as Exhibits 4 and 5 hereto, the former relating to the jurisdictional issue and the latter relating to the Rule 9(b) motion.

[3] The False Claims Act requires *qui tam* relators to serve on the United States a "copy of the complaint and written disclosure of all material evidence and information the person possesses." 31 U.S.C. § 3730(b)(2). While these are widely recognized as attorney work-product, *see e.g. United States ex rel. O'Keefe v. McDonnell Douglas Corp.,* 918 F. Supp. 1338, 1346 (E.D. Mo. 1996); *United States ex rel. Bagley v. TRW, Inc.*, 212 F.R.D. 554 (C.D. Cal. 2003), that protection obviously was waived in connection with the *Moyer-Shelton* case.

> 4. In approximately the fall of 2003, while I was still a new employee, I was preparing a program on Elidel. I observed sales representatives Nemeth, Burkett and Kistner with a document known as _Home Made Bread' which was a list prepared to present to physicians identifying the uses for the drug, Elidel, a drug approved by the FDA only for the treatment of atopic eczema. This list which was prepared for use with physicians listed several diseases, including psoriasis and seborrhea as diseases which could be treated with Elidel. When I questioned these representatives and asked for a copy of the document they refused to give it to me.

Exhibit 5, ¶ 4. Ms. Shelton's affidavit makes no further mention of Elidel.

These documents make clear that neither Ms. Moyer nor Ms. Shelton knew of any actual off-label marketing of Elidel. They knew only that some local sales representatives had a document which identified off-label uses of Elidel, and assumed that those sales representatives were engaged in actually marketing the drug for those purposes. They do not identify any doctors who were detailed with off-label information; any off-label training; any off-label detail literature; or, in fact, so much as a single detail showing that any doctor was ever marketed for off-label use of Elidel.

The same is true with respect to the *Moyer-Shelton* kickback allegations. They allege that personnel were dispersed to health insurers to minimize the cancer risk posed by Elidel. But they were unable even to allege that these personnel had contact with decision-makers from publicly-funded health care programs, a necessary predicate to a reasoned allegation of false Medicaid or Medicare claims.

On April 23, 2007, Judge Anna Diggs Taylor of the Eastern District of Michigan dismissed the *Moyer-Shelton* False Claims Act allegations on the basis that their allegations had been publicly disclosed, and under Sixth Circuit precedent, the relators could not qualify as

original sources under 31 U.S.C. § 3730(e)(4)(B).[4] Because the court's original-source decision impacted its subject-matter jurisdiction, Judge Taylor's written order (Novartis Exhibit F) addresses only that issue, finding moot the motion to dismiss predicated on Rule 9(b). At the hearing on Novartis' motions, however, Judge Taylor made this specific finding: "I will say that Rule 9(b) does require fraud to be plead with particularity ***and it has not been in this case***." Transcript of April 23, 2007 Hearing, Novartis Exhibit E, at 19 (emphasis supplied).

2. This case is not "based upon the facts underlying" *Moyer-Shelton*

This case and the *Moyer-Shelton* case have common legal theories. They both allege that Novartis violated the False Claims Act by engaging in off-label marketing of Elidel, and they both allege that Novartis paid kickbacks to high-prescribing physicians. That is where the similarity stops. This case does not allege any "home cooking" document listing off-label uses. It does not allege that sales representatives were trained to advocate "occlusive dressings" to physicians. And it does not allege that Novartis sent out truth squads to allay the fears of insurance companies regarding Elidel's carcinogenicity. Thus, this case is simply not a factual reprise of the *Moyer-Shelton.*

Moreover, the *Moyer-Shelton* relators did not make a single factual allegation of off-label marketing of Elidel by identifying any sales representative who *in fact* engaged in off-label

[4] As discussed in detail below, the original source provision of the FCA, 31 U.S.C. § 3730e(4)(B), the district courts enjoy subject-matter jurisdiction over complaints "based upon" publicly disclosed information, when she "has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section[.]" The Sixth and D.C. Circuits have added a requirement that the relator have disclosed her information to the United States prior to the public disclosure. *E.g.*, *U.S. ex rel. McKenzie v. BellSouth Telecomms., Inc.,* 123 F.3d 935, 943 (6th Cir. 1997); *U.S. ex rel. Settlemire v. Dist. of Columbia*, 198 F.3d 913, 915-916 (D.C. Cir. 1999). This Court rejected the Sixth Circuit's original-source "third prong" in *United States ex rel. Merena v. SmithKline Beecham Lab., Inc*., 114 F. Supp. 2d 352, 359-60 (E.D. Pa. 2000), and no circuit court has adopted it since.

marketing to any physician; did not identify any off-label sales message; did not identify any training or management directive to sell off-label; and did not make any allegations tending to demonstrate that off-label claims were actually submitted. Moreover, the only off-label marketing that Moyer and Shelton allege may have occurred related to "psoriasis and seborrhea." Novartis Exhibit B at ¶ 12(b).

By sharp contrast, Mr. Galmines alleges "an aggressive campaign to promote its prescription topical immunomodulator cream, Elidel®, for off-label use in the treatment of children under the age of two, for first-line use, and for chronic use." Compl. ¶ 2. With respect to the most significant of these allegations—marketing to children under the age of two—Mr. Galmines alleges that prior to the product launch of Elidel, on or about January 18, 2002, he and his colleagues were trained that "Elidel should replace all mid-level steroid usage" were directed to tell their customers to use Elidel instead of steroids on infants under the age of two; and were directed to tell physicians that Elidel "must be safe" for use on infants. Compl. ¶¶ 56-58. Mr. Galmines and his colleagues were instructed to push sales of Elidel for use in infants, to push sales of Elidel as a first-line, rather than second-line, therapy, and were instructed to push Elidel for chronic, rather than short-term, intermittent use. *Id*. ¶ 54. He alleges that he was provided with marketing literature which discussed the "safety" of coating 92% of infants' bodies with Elidel, a known carcinogen, and "[o]n or about September 25, 2002, he was instructed by [his manager] to carry two different promotional binders in his car; one which contained only approved detail pieces and a second that included off-label literature. Mr. Burnitz explained that by doing so, Mr. Galmines could provide the approved binder if he was ever approached by the FDA.'" Compl. ¶ 69.

Mr. Galmines identifies specific marketing pieces and messages relating to the marketing of Elidel for use on infants, as well as for long-term use and chronic use (*Id*. ¶¶ 60-64, 68, 72-75, 82-83) ; identifies specific post-launch "Phase II" training at which he was directed to market for infant use and other off-label purposes (*Id*. ¶¶ 71, 77, 88,91, 95); and was directed to tout Elidel as preferable to topical steroids (*Id*. ¶¶ 57-58, 78) even though no scientific support for that assertion exists—and, in fact, it appears to be a flat-out lie.[5]

Mr. Galmines was also directed to market to physicians using off-label literature, including several articles published by Novartis-sponsored physicians who claimed that Elidel was appropriate for use on infants. *Id*. ¶¶ 71-73. Moreover, he alleges that he personally developed a marketing document called "The Atopic Triad," which referenced the recommendation in one of the off-label articles that Elidel be used on children—and that his manager put his own name on Mr. Galmines' document and "rolled it out as a regional initiative." *Id*. ¶¶ 82-83.

For his success marketing Elidel, Mr. Galmines was rewarded with a trip to New Orleans in May, 2003, where he trained sales representatives from all U.S. districts in "The Atopic Triad." *Id*. ¶ 86. At this meeting, he was told by Novartis' principal trainer "that the sales representatives who were doing the best with Elidel were selling off-label and for infant uses." *Id*. ¶ 87. At the same training meeting, "Representatives were instructed to advise physicians

[5] In fact, strong scientific evidence exists to the contrary. In 2007, months after the complaint in this case was filed, an article was published which examined the results of studies comparing Elidel's active ingredient, pimecrolimus, to topical corticosteroids. This "meta-study" found that "pimecrolimus was less effective than potent corticosteroids in atopic dermatitis" and that "pimecrolimus caused more burning of the skin than topical corticosteroids." Also, "12 scenarios of treatment comparing topical corticosteroids and pimecrolimus were modeled, resulting in the superiority of corticosteroids, which were both cheaper and more effective" than Elidel. Chrysovalantis Korfitis, et al., *Pimecrolimus versus topical corticosteroids in dermatology*, Expert Opin. Pharmacother. *(2007) 8(10):1565-1573 at 1567* (Exhibit 8).

that kids were "practically bathed in Elidel" with no effect on their blood serum levels." *Id.* ¶ 88. At a subsequent regional sales meeting, Mr. Galmines and his colleagues were instructed "not to worry" about detailing off-label, because the "chances of getting caught were a million to one." *Id.* ¶ 91. Novartis also directed Mr. Galmines' manager to market Elidel off-label. *Id.* ¶ 92.

Most shocking, perhaps, is that in May 2005, after the FDA proposed putting a Black Box Warning against using Elidel on infants, Mr. Galmines was directly "instructed to target Elidel sales to pediatricians, to assert that Elidel was safe for infants, and to heavily detail [an infant] reprint" and "not advise physicians that infants with 92% body coverage of Elidel for a year showed negligible blood-serum levels." *Id.* ¶ 95. A year later, in late February 2006, Mr. Galmines was reprimanded for not having off-label literature in his kit, and for telling a physician not to prescribe Elidel for use on children under two. *Id.* ¶ 96.

Mr. Galmines' kickback allegations are equally detailed. He sets forth detail that described how physicians, including specifically named physicians such as Drs. Koya, Blondon, and Sarmiento, were given fancy dinners, wine, and travel opportunities in exchange for writing Elidel prescriptions. Compl. ¶¶ 118-119; 134-139. Novartis also regularly targeted high-prescribing physicians and potentially high prescribing physicians with opportunities to make money through "honoraria,", preceptorships (when Novartis pays a doctor to allow a drug salesperson to join the doctor as she treats patients), and in particular, speaking engagements (many of the speaking events for which physicians were paid never occurred). Compl. ¶¶ 120-121, 123-133, 140-141. Mr. Galmines also identifies specific kickbacks provided to the following physicians: Drs. Memar, Coynik, Koya, and Bukhalo. Compl. ¶¶ 126, 131, 141.

3. The *Moyer-Shelton* complaint is legally insufficient to trigger the first-to-file provision

There is no sound reason to hold that the *Moyer-Shelton* complaint triggered the first-to-file bar with respect to the off-label marketing of Elidel. They knew none of the central facts of this case: They do not allege marketing for infant use, for first-line use, or for chronic use. They did not identify a single sales representative who actually engaged in off-label marketing, a single trainer or manager who advocated off-label marketing, or a single physician to whom Novartis personnel delivered off-label messages. Even though Ms. Shelton advised that she was tasked with marketing Elidel, no reference is made to the off-label messages, materials, or strategies as discussed in precise detail by Mr. Galmines. And although they have general knowledge that Novartis marketed its drugs by paying kickbacks to physicians, there is no indication that they knew that such was done with respect to Elidel; again, no salespeople, physicians, dates, amounts, or locations are identified.

As the cases, the history of the False Claims Act, and common sense make clear, the purpose of the first-to-file clause is to benefit the United States–not defendants. The United States certainly benefits when the first-to-file clause is used to eliminate late-filed relators whose complaints, no matter how detailed, mirror ongoing investigations, as was true in *LaCorte.* Here, there is simply no ~~t~~here" to the *Moyer-Shelton* complaint: Not only was the case dismissed for lack of subject matter jurisdiction with a specific finding at the hearing that the complaint did not satisfy Rule 9(b),[6] but there is no basis to conclude that the United States should have committed the massive investigative resources involved in a marketing case against a pharmaceutical company. At the end of the day, to the extent any Elidel-related schemes can be discerned at all,

[6] Transcript of April 23, 2007 Hearing, Novartis Exhibit E, at 19.

they are simply different from those alleged by Mr. Galmines. There is not a single aspect of the defendant's position which squares with the reasons for the first-to-file provision. Dismissal would be contrary to *LaCorte*, and Novartis' motion to dismiss based on the *Moyer-Shelton* complaint should be denied.[7]

II. BECAUSE MR. GALMINES IS AN ORIGINAL SOURCE WHO BROUGHT NEW, DETAILED INFORMATION ABOUT NOVARTIS'S RELENTLESS CAMPAIGN TO SPREAD CARCINOGENS ON INFANTS, HE IS AN ORIGINAL SOURCE OF HIS ALLEGATIONS AND THE COURT HAS JURISDICTION

At the time the complaint in this case was filed, the False Claims Act provided that only an "original source" relator could bring a *qui tam* complaint "based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing," certain government reports, or "the news media, unless the person bringing the action is an original source of the information." Former 31 U.S.C. § 3730(e)(4)(A).[8]

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[7] Relator notes that the Seventh Circuit recently concluded that a case dismissed under the first-to-file provision should be dismissed without prejudice, so that the relator can refile it if circumstances otherwise permit. *United States ex rel. Chovanec v. Apria Healthcare Group Inc*., 606 F.3d 361, 365 (7th Cir. 2010). We respectfully submit that should the Court somehow find that, despite *LaCorte* and the Sixth and First Circuit decisions, as well as the informed position of the United States (Exhibit 3), the *Moyer-Shelton* complaint dictates dismissal here, Judge Easterbrook's decision is correct, and any dismissal should be without prejudice.

[8] The text of 31 U.S.C. § 3729(e)(4)(A)-(B)(2009) reads:

> (4) (A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly

Novartis shows in great detail that its calculated decision to violate the FDA's label requirements and market the carcinogenic Elidel cream for use on infants without regard to the widespread safety problems with such use as identified by the FDA resulted in a raft of personal-injury lawsuits by parents of babies who developed tumors. Novartis also touts the fact that the Food and Drug Administration convened a round of hearings, the purpose of which was to explore the explosion in off-label prescribing of Elidel. This, of course, is no secret: These hearings, and the resulting boxed warning against using Elidel on infants, are alleged in Mr. Galmines' complaint, at ¶¶ 104-15.

There is delicious irony in Novartis' position before this Court that its off-label marketing efforts were widely known in 2006, since at the FDA hearing conducted in February 2005, Dr. Carle Paul, Novartis' Elidel Medical Director, spoke at the Pediatrics Advisory Committee hearing, during which he specifically and categorically denied that Novartis engaged in off-label marketing of Elidel. When asked if Novartis was "doing anything to discourage off-label use," Dr. Paul relied: "Of course. As we encourage label use, we discourage off-label use." Dr. Paul further told the FDA that management at Novartis "makes sure" that "[t]he promotional activities with Elidel® are done according to the label." Exhibit 1, tr. p. 169. Nonetheless, while Mr. Glamines's allegations were in no manner consistent with the plain meaning of the words "based upon" those public disclosures (for they were based entirely on his own experience marketing Elidel from the date of launch through the Boxed Warning), he recognizes that there were public disclosures of allegations that Novartis was marketing Elidel off-label before he filed the complaint in this case, as well as allegations that Novartis was paying a variety of forms

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disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

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of compensation to high-prescribing physicians.

The issue rests, then, on the question of whether Mr. Galmines was an "original source" of his allegations. Under the Act as it was in 2006, an original source is one "who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." Former 31 U.S.C. § 3730(e)(4)(B).

In *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 335-336 (3d Cir. 2005), the court explained:

> The Third Circuit has interpreted direct to mean "marked by absence of an intervening agency, instrumentality, or influence: immediate.'" *Stinson,* 944 F.2d at 1160 (*quoting* Webster's Third New International Dictionary 640 (1976)). Other courts have interpreted direct to mean 'first-hand,' *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 690 (D.C. Cir. 1997), 105 F.3d at 690, 'seen with the relator's own eyes," *Wang ex rel. United States v. FMC Corp*., 975 F.2d 1412, 1417 (9th Cir. 1992), "unmediated by anything but [the relator's] own labor,' *id*.; *see also United States ex rel., Fine v. MK- Ferguson Co*., 99 F.3d 1538, 1547 (10th Cir. N.M. 1996); *United States ex rel. Devlin v. California*, 84 F.3d 358, 360-61 (9th Cir. 1996), and 'by the relator's own efforts, [**24] and not by the labors of others, and . . . not derivative of the information of others,' *United States ex rel. Hafter v. Spectrum Emergency Care, Inc*., 190 F.3d 1156, 1162 (10th Cir. 1999).

"Independent" means that "knowledge of the fraud cannot be merely dependent on a public disclosure." *Id*. at 336-37. Here, Mr. Galmines' knowledge of Novartis' off-label Elidel marketing schemes and its kickbacks to physicians come straight from his own experience, and from the mouths of Novartis managers, trainers, and colleagues, all in the normal course of business. We respectfully submit that there is no basis for any claim that Mr. Galmines' knowledge is not both "direct" and "independent."

Novartis does not appear to refute the directness or independence of what Mr. Galmines learned during his many years of marketing Elidel. Rather, it first takes issue with the fact that

the complaint does not allege that Novartis made specific misrepresentations ―to the Government." MTD at 26, quoting *United States ex rel Mistick PBT v. Hous. Auth. of City of Pittsburgh,* 186 F.3d 376, 388 (3d Cir. 1999). While this is not so (consider, *e.g.*, Dr. Paul's apparent lies to the Food and Drug Administration), it is a patent red herring. Novartis did not submit the claims at issue at all. Rather, the essence of a case alleging that off-label marketing led to FCA violations is that the marketing scam caused the submission of false claim by third parties. What could not be clearer is this: Mr. Galmines has intimate and detailed knowledge of the off-label scheme deployed by Novartis from well before the Elidel launch, until well after the Black Box warning was required by the FDA. Novartis would hinge the Court's jurisdiction on Mr. Galmines' ability to identify things he could not have known about: The particular pharmacy claim for a particular Medicare or Medicaid patient. Mr. Galmines respectfully urges that the Court base this determination on what Mr. Galmines *does* know: That a major multinational corporation willfully ordered its large national sales force to falsely tell physicians that Elidel was safe for infants―"Doctor, what else would you use? Surely not steroids!"―and that the FDA must agree, because it allowed infant data to be included on the label―so it "must be safe." Compl. ¶¶ 57-58.

There can be no credible argument that Mr. Galmines does not have direct and independent knowledge of his allegations of illegal conduct by Novartis, and that is precisely what the statute required. Novartis' argument is really a Rule 9(b) argument clothed as an original source claim, and to that extent, is addressed elsewhere.

The other requirement of the original source provision is that the relator have "voluntarily provided the information to the Government before filing an action under this section which is based on the information." The Complaint alleges the jurisdictional predicate,

asserting that Mr. Galmines qualifies as an original source. Compl. ¶ 8. Novartis seeks to add to this language, asserting that Mr. Galmines must also allege that he

> "voluntarily provided the information to the Government" 31 U.S.C. § 3730(e)(4)(B) (emphasis added)–and did so before any public disclosure of that information. *U.S. ex rel. Settlemire v. Dist. of Columbia*, 198 F.3d 913,915-16 (D.C. Cir. 1999); *U.S. ex rel. McKenzie v. BellSouth Telecomms., Inc.*, 123 F.3d 935,943 (6th Cir. 1997).

MTD at 28.

Novartis overreaches badly by asking this Court to follow *Settlemire* and *McKenzie* for the proposition that Mr. Galmines had to disclose to the government before any public disclosure occurred; as noted above, this Court rejected the Sixth Circuit's original-source "third prong" in *United States ex rel. Merena v. SmithKline Beecham Lab., Inc*., 114 F. Supp. 2d 352, 359-60 (E.D. Pa. 2000). In fact, these extra-statutory holdings are prudential orphans, having been rejected by those courts which have considered them for the past 12 years. *E.g*., *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P*., 579 F.3d 13, 22-23 (1st Cir. 2009). Because Novartis has provided no analysis of these cases which would lead to a different result, Relator moves on.

Novartis apparently would have it that a relator seeking to establish jurisdiction as an original source must provide detailed information of his or her having voluntarily provided *qui tam* allegations to the United States prior to filing in order for the complaint to escape dismissal pursuant to Rule 12(b)(1). Novartis cites no authority for this proposition, and we respectfully disagree with its position unless the Court determines that an evidentiary proceeding is necessary. Indeed, the First Circuit recently held

> Blackstone only argues that Hutcheson insufficiently alleged that she "provided the information to the Government before filing" as required by 31 U.S.C. § 3730(e)(4)(B). Hutcheson's complaint stated that she disclosed the allegations to the United States Attorneys' Office for the Middle District of Florida in the

_Summer of 2006' _prior to filing.' This is more than enough.

United States ex rel. Hutcheson v. Blackstone Medical, Inc., — F.3d —, —, 2011 U.S. App. LEXIS 10972 , at *19 (1st Cir. June 1, 2011). Relator respectfully submits that the allegations of the complaint in this regard are sufficient. However, were the Court to disagree, Relator asks leave to amend the complaint (or demonstrate at an evidentiary hearing) that:

1. The complaint in this case was filed on July 21, 2006.

2. In early July, 2006, Counsel for Relator, Frederick M. Morgan, Jr., made contact by telephone with James Sheehan, Esq, U.S. Attorney's Civil Chief, and discussed in as much detail as Mr. Sheehan's schedule permitted the information possessed by Mr. Galmines regarding the off-label marketing and kickback activities of Novartis in connection with the prescription drug, Elidel.

3. On July 13, 2006, at 2:41 p.m., a copy of the complaint was provided by electronic transmission to Kathleen Merriwether, Esq., Assistant United States Attorney for the Eastern District of Pennsylvania.

Relator respectfully submits that, in the words of the First Circuit, —[t]his is more than enough."

III. RELATOR'S WELL-PLED ALLEGATIONS ADEQUATELY STATE A CLAIM FOR RELIEF UNDER THE FCA

A. Relator has properly alleged *how* the claims Novartis caused third parties to submit were knowingly false and fraudulent

Novartis argues that Relator has not alleged *how* Novartis' claims submitted pursuant to its off-label campaign were false or fraudulent because Relator has not alleged that the claims for reimbursement contain facially false or fraudulent statements, —such as the age of patient to whom it was prescribed, the reason for the Elidel use; or whether other products were previously

used or deemed inadvisable," MTD at 32. While it is true that the claims for reimbursement of Elidel prescriptions contain none of this information (in fact, the physical claims for prescription drug reimbursements contain no information whatsoever indicating the purpose(s) for which the prescription was written). This is of no moment. A claim's falsity is not dependent on whether it states a lie on its face. *United States ex rel. Hutcheson v. Blackstone Medical, Inc*., — F.3d — 2011 U.S. App. LEXIS 10972 , at *23 (1st Cir. June 1, 2011) ("[t]he text of the FCA does not refer to 'factually false' or 'legally false' claims").

In the context of off-label marketing cases, the fraudulent nature of the claims is derived from the defendant's conduct (here, the illegal off-label message promoted by Novartis) and its relationship to inducing payment of a claim to which it is not entitled (here, causing a physician to write an off-label prescription which is subsequently submitted to a federal health care program for reimbursement). *Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975) (holding that knowing submission of Medicare claims for services that are not covered and payable under the Medicare Act is a violation of the FCA), *cert. denied sub nom. Peterson v. Mathews*, 423 U.S. 830, 46 L. Ed. 2d 47, 96 S. Ct. 50 (1975). Claims may be false if they "claim reimbursement for services or costs that . . . are not reimbursable." *U.S. ex rel. Walker v. R & F Props. of Lake County, Inc*., 433 F.3d 1349, 1356 (11th Cir. 2005).

Off-label schemes result in false claims to federal health care programs because off-label marketing is illegal (Compl. ¶¶ 13-17) and statutory preconditions limit federal health programs' payments for prescription drugs that are the result of, or were influenced by such unlawful marketing activities (Compl. ¶¶ 23-24; 33; 146-149).[9] *U.S. ex rel. Underwood v. Genentech, Inc.,* 720 F. Supp. 2d 671 (E.D. PA 2010)(denying defendant's motion to dismiss *qui tam* suit

[9] The statute makes clear that this is so regardless of the truth or falsity of the off-label message.

alleging off-label promotion caused prescriptions to be written for Medicare/Medicaid patients, resulting in the presentation of many millions of dollars in false claims to the government.); *U.S. ex rel. Franklin v. Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *17-18 (D. Mass. Aug. 22, 2003)(liability attaches where a pharmaceutical manufacturer knowingly engages in an illegal off-label marketing scheme which causes providers to submit non-reimbursable prescription drug claims to government healthcare programs for payment.); *U.S. ex rel. Strom v. Scios, Inc.,* 676 F. Supp. 2d 884, 891 (N.D. Cal. 2009) (adequately alleging false statement in support of false claim where relator alleged pharmaceutical drug —was not, in fact, effective when used for the off-label purpose" because —a prescription of [the drug] in a context where it is not ‗reasonable' or ‗necessary' would be statutorily ineligible for reimbursement"); *U.S. ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 409 (D. Mass. 2010) (complaint adequately alleged implied certification of claims submitted to Medicare in violation of the FCA where —there was no medically accepted indication" for drug prescribed in certain patient populations) (citation omitted).[10] The specific regulations that create liability here are discussed in depth below.

1. FDA laws and regulations bar drug manufacturers from marketing or promoting a drug for indications or patient populations beyond those specifically approved by the FDA

FDA laws and regulations prohibit drug manufacturers from marketing or promoting a drug for indications in unapproved patient groups. Under the Food, Drug and Cosmetics Act (the —FDCA"), 21 U.S.C. §§ 301-97, a pharmaceutical manufacturer cannot market a drug in the United States unless it demonstrates to the satisfaction of the FDA that the drug is safe and

[10] *See also, U.S. v. Incorporated Vill. of Island Park*, 888 F. Supp. 419, 439 (E.D.N.Y. 1995) (—[T]he [FCA] is violated not only by a person who makes a false statement or a false record to get the government to pay a claim, but also by one who engages in a fraudulent course of conduct that causes the government to pay a claim for money.").

effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Prescription drug approval is the final step in a multi-year process of study and testing. When the FDA approves a drug, the approved indication is for treatment of a specific condition and/or a specific patient population for which the drug has been tested and found by the FDA to be safe and effective. 21 U.S.C. §§ 352, 355(d). The FDCA mandates that the FDA regulate prescription drug labeling, requiring the agency to "promote the public health" by "ensur[ing] that ... drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). Manufacturers seeking to market or promote an approved drug for additional uses outside of the approved label must resubmit the drug for another series of clinical trials similar to those which supported the initial approval. Food and Drug Administration Modernization Act of 1997 ("FDAMA"), 21 U.S.C. § 360aaa(b), (c).

Use of an approved drug outside of the label (including indication and usage, dose, and route of administration) is referred to as an "off-label" use. The FDCA prohibits drug manufacturers from marketing or promoting a drug for off-label uses, see 21 U.S.C. §§ 331 & 352, but does not prohibit physicians from prescribing an approved drug for such use. Even when a drug is indicated for a specific use, the FDA deems the use of the drug to treat a patient population not specified on the label to be off-label. *See Ass'n of Am., Physicians & Surgeons, Inc. v. United States FDA*., 226 F. Supp. 2d 204, 206 (D.D.C. 2002) ("[O]ff-label use is the prescription of a drug by a doctor for a condition not indicated on the label or for a dosing regimen or patient population not specified on the label.") Accordingly, manufacturers may only advertise or otherwise promote a drug for approved uses, and among the patient populations for whom it is approved and has been shown to be safe and effective, 21 C.F.R. § 201.100(d). Any promotion or marketing of a drug for an off-label indication, including use in an off-label patient population, is considered to be false and misleading representation in violation of both the FDCA

and FDA regulations. 21 U.S.C. §331(d) (prohibiting distribution of drug for non-approved uses); *id*. at §331(a) (prohibiting distribution of a misbranded drug).[11] Compl. ¶ 16.

In addition to prohibiting manufacturers from directly marketing and promoting a drug's unapproved use, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. The FDA regulates two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products; and (2) manufacturer support for CME programs that focus on off- label uses. It is unlawful for manufacturers to disseminate such medical and scientific publications or to provide support for such CME programs when the underlying indications or uses are not approved by the FDA. 21 USC §§ 360aaa(b) and (c).

2. Prescription drug reimbursement by government healthcare programs is strictly limited to medically accepted indications

While the FDA does not decide which drugs and uses will be paid for by federal healthcare programs, Congress has integrated FDA drug restrictions into federal health program restrictions regarding what drugs will be covered and paid.[12] Compl. ¶ 23. As a condition of

[11] Pursuant to 21 U.S.C. § 352(f), a drug is "misbranded" if its labeling does not bear "adequate directions for use." FDA regulations provide that "adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended[,]" 21 C.F.R. § 201.5, and further provide that a drug's "intended use" is determined by considering the "objective intent of the persons legally responsible for the labeling of the drugs[,]" as evidenced by the "labeling claims, advertising matter, or oral or written statements by such persons or their representatives." 21 C.F.R. § 201.128. Consequently, if a manufacturer or its representatives promote the "off-label" use of a drug, then the drug's labeling will not bear adequate directions for the "purposes for which it is intended", and the drug will be considered to be "misbranded". *United States v. Caronia*, 576 F. Supp. 2d 385, 389 (E.D.N.Y. 2008) (internal citation omitted).

[12] In *U.S. ex rel. Franklin v. Parke-Davis,* 147 F. Supp. 2d 39, 51-52 (D. Mass. 2001), the district court specifically rejected the defendant's argument that the plaintiff, who alleged an off-label marketing scheme similar to the one here, could not establish liability under the FCA because the

payment for Medicare and Medicaid reimbursement, prescription drug claims may only be submitted for "covered outpatient drugs," that are the subject of a rebate agreement with a pharmaceutical manufacturer. 42 U.S.C. §§1396(b)I)(10), 1396r-8(k)(2),(3). To be covered, a drug must be used for a "Medically-Accepted" indication, meaning approved by the FDA and set forth in the drug's label, or supported in certain published compendia authorized by federal prescription drug reimbursement rules. 42 U.S.C. §§ 1396r-8(k)(2),(3),(6); 1396r-8(g)(1)(B)(I). Compl.¶ 24.

The FDA statutes along with the statutory prohibitions on reimbursement by federal healthcare programs establish that that prescriptions resulting from a pharmaceutical's off-label marketing campaign are not covered and payable under Medicare, Medicaid of other federally funded healthcare programs. Here, it was Novartis' deliberate campaign to market Elidel for uses specifically disapproved the FDA and which posed significant safety and health risks to infants and others that renders claims for reimbursement resulting from the illegal marketing false and fraudulent under the FCA. Compl. ¶¶ 146-149.

FDCA does not provide the government with a civil damage remedy to enforce the ban on off-label marketing. The court explained that "while the FCA cannot be used to enforce compliance with every federal law or regulation (omitting internal citation) …it *can* be used to create liability where failure to abide by a rule or regulations amounts to a material misrepresentation made to obtain a government benefit …Thus, the failure of Congress to provide a cause action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government in violation of 31 U.S.C. § 3729(a)." *See also United States v. White*,765 F.2d 1469, 1479-80 (11th Cir. 1985) (FCA case based on altered time cards submitted in violation of the Truth in Negotiations Act); *Pickens v. Kanawha River Towing*, 916 F. Supp. 702, 705-06 (S.D. Ohio 1996) (rejecting defendant's argument that remedies under federal Clean Water Act preempted relator's action under the FCA); *United States ex rel. Fallon v. Accudyne Corp*., 880 F. Supp. 636, 638 (W.D. Wis. 1995) (allowing FCA action based on failure to comply with environmental standards); *United States v. Incorporated Vill. of Island Park, 888 F. Supp. at 434-36* (same with regard to failure to comply with non-discrimination requirements).

3. Novartis' false and fraudulent statements to healthcare providers and to the public

Relator's job at the pleading stage is to identify the fraudulent conduct, which it alleges causes the submission of false claims to the government. To this end, Novartis argues that "even assuming *arguendo* that a claim submitted to a government healthcare program could be rendered false because of a false statement made to a physician, Relator fails to identify a single statement made by anyone at Novartis to an Elidel prescriber that *was* false or misleading." MTD at 33. This is flatly false. As articulated in copious and concise detail in the complaint, Novartis disseminated a variety of messages directly to physicians to promote unapproved off-label use of Elidel for: (a) infants under two years of age; (b) as a first line treatment; and (c) for chronic use.[13] Novartis' off-label messages were replete with false and misleading statements

[13] Novartis argues in footnote 12 of its MTD that under section 3729(a)(2), that Mr. Galmines is required to allege that Novartis intended to rely on a false statement based on the ruling in *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 672 (2008). This is not so.Congress amended the FCA in 2009 through passage of the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 111-21, 123 Stat. 1617. FERA, in part, replaced the former subsection (a)(2) with new subsection (a)(1)(B). The new subsection (a)(1)(b) no longer contained the requirement that false or fraudulent statements or records be used or created *to get* a false or fraudulent claim paid or approved by the government, but instead created liability where such statements or records are material to false or fraudulent claims. In response to *Allison Engine*, Congress made the new subsection (a)(1)(B) retroactive to "claims" pending as of June 7, 2008. While the Third Circuit has not reached the issue, other courts have correctly rejected Novartis' implicit assertion that "claims" refers to claims for payment, and rather held that claims refers to causes of action. *E.g., United States ex rel. Kirk v. Schindler Elevator Corp.,* 601 F.3d 94, 113 (2d Cir. 2010), *rev'd on other grounds*, 131 S. Ct. 1885 (2011); *United States ex rel. Steury v. Cardinal Health, Inc*., 625 F.3d 262, 267 n.1 (5th Cir. 2010). Mr. Galmines' claims are still pending, and thus subject to the new subsection (a)(1)(B) requiring a material connection between Novartis' marketing and the resultant claims for reimbursement of off-label Elidel prescriptions. Mr. Galmines' complaint aptly meets this requirement. Moreover the "to get" requirement ultimately goes to the defendant's intentions. Here, Mr. Galmines clearly alleges that Novartis intended, through its schemes, to get prescriptions reimbursed by federal healthcare providers.

directly contrary to the FDA's findings regarding the safety of Elidel for off-label purposes, as well as to its overall safety and efficacy, particularly as compared to the safety of steroids (discussed at Compl. ¶¶ 34-49). Furthermore, Novartis routinely omitted important information regarding Novartis' efficacy and safety. A false statement need not be an affirmative misrepresentation; a material omission will suffice: "[H]alf the truth may obviously amount to a lie, if it is understood to be the whole." W. Page Keeton, *Prosser & Keeton on the Law of Torts* § 106, at 738 (5th ed. 1984).[14]

One key method Novartis used to disseminate its off-label messages was through visual aids, created by Novartis and routinely used by its sales representatives. These visual aids included the following messages promoting Elidel as a first-line treatment and for long term use: "[use ELIDEL® twice daily at the **first signs or symptoms** of a flare and through resolution"; "[t]reat early with ELIDEL® for long-term control"; "[use ELIDEL® at the first signs or symptoms of flare recurrence through resolution to control eczema"; and urging patients to use Elidel® "[w]hen you want or need to avoid corticosteroids for your mild to moderate eczema patients" and identifying "**first signs and symptoms"** as being "[a]hint of itchiness," "[a] spot of redness," [t]he slightest bump," and "[t]he tiniest tingle." Compl. ¶ 76.

Regarding the use of Elidel for infants under two years of age, sales representatives were trained to respond in the affirmative and falsely state in contradiction of the FDA's findings, that

[14] *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir. 1999) (observing that a half-truth may amount to a false statement under the FCA); *U.S. ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995) (finding that false progress reports may constitute false statements under the FCA); *U.S. ex rel. Fry v. Guidant Corp.*, No. 03-842, 2006 U.S. Dist. LEXIS 65702, at *35-36 (M.D. Tenn. Sept. 13, 2006) (finding representation was rendered false by concealment of material information); *U.S. ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 43 (D. Mass. 2000) (an "omitted material fact," such as the existence of illegal kickbacks, may be actionable under the FCA).

Elidel was a safer alternative than steroids, Compl. ¶¶ 49, 57; and to state that the infant study data included in the Elidel labeling evidenced Elidel's safety for this population under two years. Compl. ¶¶ 58-59, 65, 77. Additionally, Novartis trained its sales representatives to market the Novartis -sponsored, Eichenfield and Kapp scientific studies in a variety of formats (*e.g.* through reprints, press releases, and detail pieces). These studies promote off-label use of Elidel in infants and omit entirely any identification or acknowledgement of the FDA-determined risk assessment in this age population. Compl. ¶¶ 60-64, 72-75, 82-83. Likewise, in its advertising directly to the public Novartis states that for 60% of patients, eczema symptoms develop before age one, without mention of the FDA's black box warning against using Elidel on infants or any of its other limitations. Compl. ¶¶ 99-100. Similarly, a press release available to the public on Novartis' website claimed that treatment of infants with Elidel "improved parents quality of life." Compl. ¶ 73.

A particularly nefarious aspect of Novartis' marketing campaign was to capitalize and foster "topical corticosteroid phobia", despite the complete lack of data comparing the safety and efficacy of Elidel to topical corticosteroids. Compl. ¶¶ 49,57, 78, 99. Similarly, Novartis promoted the dangerously misleading statements that Elidel has negligible effects on blood serum levels even when infants "practically bathed" in Elidel. Compl. ¶¶ 68, 88. This is dangerously misleading since Elidel is absorbed into the lymphatic system and not the blood system.

Finally, Novartis also never disclosed to physicians that its marketing and promotion was illegal. It never disclosed to the United States that it illegally promoted non-covered drugs. Certainly, it routinely provided rebate reports to the United States for sales for non-covered uses

of its drugs without disclosing that federal healthcare dollars were used for non-reimbursable prescriptions. These are all false statements in violations of § 3739(a)(1)(B).

4. Novartis' knowledge of the false and fraudulent nature of the claims it caused third parties to submit via its off-label marketing campaign

The FCA's knowledge definition for culpable statement of mind includes not only actual knowledge, but also deliberate ignorance and reckless disregard. 31 U.S.C. § 3729(b)(A). There is no obligation to allege or prove specific intent to defraud. *Id.* at § 3729(b)(B). Rule 9(b) allows conditions of mind to be pled generally. *In re Cardiac Devices Qui Tam Litig.,* 221 F.R.D. 318, 339 (D. Conn. 2004), *rev'd on other grounds sub nom.* This is because it is widely recognized that "it would be unworkable and unfair to require great specificity pleading scienter, since a plaintiff realistically cannot be expected to plead a defendant's actual statement of mind." *Stern v. Leucadia Nat'l Corp*., 844 F.2d 997, 1004 (2d Cir. 1988)(internal citation omitted); and that inquiries into the degree of a defendant's knowledge typically cannot be resolved at pleading state. *In re Cardiac Devices* 221 F.R.D. 318 at 339.

Nonetheless, Novartis argues that Relator has not sufficiently alleged that Novartis had knowledge that its off-label campaign resulted in false claims to the government, MTD at 32, and suggests in a footnote that this is because the claims were ultimately submitted by pharmacies after doctors prescribed Elidel. *Id*. at n.19. A party who causes an innocent third party, such as a physician or pharmacist, to submit false claims does not escape liability. The Third Circuit addressed the core principal of the FCA that it encompasses those who "knowingly assist" in causing the government to pay out claims grounded in fraud, including claims in violation of a prerequisite to obtaining payment. *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004) (citing *inter alia.*, *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) and *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997)).

Applying this principle to healthcare claims, the Third Circuit followed the Supreme Court's decisions in *Marcus* and *U.S. v. Bornstein*, 423 U.S. 303 (1976), in which subcontractors were held liable for causing a prime contractor to submit a false claim, and held:

> It does not appear from the opinion of the Court in either [*Marcus v.*] *Hess* or *Bornstein* that the party actually presenting the claims to the government was aware of the fraudulent conduct. This was not a matter material to the Court's analysis, however. Given the Court's view that the crucial issue was whether the defendants knowingly assisted in the presentation of false claims, the knowledge and conduct of the defendants were what mattered and the outcome did not turn on whether the actual presenters were ~~"d~~duped" or participated in the fraudulent scheme.

Schmidt, 386 F.3d at 243-44. Indeed, as it has frequently been held in FCA cases based on off-label marketing, ~~"I~~t~~he~~ participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an **intended** consequence of the alleged scheme of fraud" *U.S. ex rel. Kennedy v. Aventis Pharms., Inc*., 610 F. Supp. 2d 938, 944 (N.D. Ill. 2009)(quoting *Franklin,* 147 F. Supp. 2d at 52-53 (emphasis supplied).

Mr. Galmines has squarely alleged that Novartis knew that its highly orchestrated, aggressive off-label campaign was both illegal and that it caused prescriptions for off-label purposes to be written and submitted to insurers. Compl. ¶ 2. Mr. Galmines clearly set forth allegations that Novartis designed its marketing messages to increase the sale of Elidel for unapproved uses, and instructed its sales representatives to regularly use materials containing these messages when detailing physicians. Novartis stated when its launched Elidel that it planned for Elidel to ~~"r~~eplace all mid-level steroid usage" and further stated in 2004 that one of primary sales goals was to sell Elidel for first- line and long-term use. Compl. ¶¶ 56, 92. Novartis was well aware that its marketing activities included off-label messages that were illegal because the FDA had specifically denied Novartis' request for approval for use in children under two years of age as well as for long term and first-line treatment. Compl. ¶¶ 34-49.

Reflecting this knowledge, Novartis announced that it planned to hold further discussions with the FDA to seek approval for an infant indication. Compl. ¶ 70. Because it was aware that off-label marketing is illegal, Novartis ordered its sales representatives to keep two promotional binders when making sales calls -- one containing only FDA approved detail pieces to show to the FDA if approached, and a second binder containing the unapproved promotional materials to use when detailing physicians. Compl.¶ 69. Further illustrating Novartis' knowledge of the illegality of its marketing campaign, Relator was specifically instructed by his supervisor to use the unapproved Kapp reprint to detail Elidel to physicians for use in infants under two, and was told "not to worry" because the "chances of getting caught were a million to one." Compl. ¶ 91.

Second, Mr. Galmines has included allegations showing that Novartis had actual knowledge that its marketing campaign resulted in vast amounts of off-label prescriptions that were submitted to health care insurers, including federally funded health care programs. Novartis fastidiously tracked the success of its off-label campaign and routine kickbacks. Compl. ¶¶ 97, 132. Novartis attributed the explosive growth in Elidel sales specifically to its marketing campaign, citing: "effective positioning and messaging," "strong field force execution," and effective DTC (Direct to Consumer advertising)." Compl. ¶ 93. In particular, Novartis managers attributed 20% of Elidel prescriptions written for children under two years of age. Compl. ¶ 116. Relator was also told by a national sales trainer that the most successful representatives were those selling Elidel off-label for infant use. Compl. ¶ 87.

Based on these allegations, it is beyond doubt that Relator has adequately pleaded Novartis' scienter under the FCA – regardless of whether knowledge is considered to be deliberate ignorance, reckless disregard, or even the actual knowledge .

B. Relator has properly alleged that Novartis caused third parties to submit false and fraudulent claims to federally funded healthcare programs

As the Supreme Court has explained, in enacting the FCA, "Congress wrote expansively, meaning '…to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Cook County, Illinois v. United States ex rel. Chandler*, 538 U.S.119, 129 (2003)(quoting *United States v. Neifert-White Co*., 390 U.S. 228, 233 (1968)). Accordingly, a violation of the FCA occurs not only when a person "knowingly presents …a false or fraudulent claim for payment or approval" or "knowingly makes or uses … a false record or statement material to a false or fraudulent claim", but also when a person *causes another* to do so. 31 U.S.C. §3729(a)(1)(A) and (a)(1)(B). In the Third Circuit, a plaintiff is required to plead that the conduct of the defendant was a "substantial factor" in causing a false claim to be submitted to the government. *U.S. ex rel. Schmidt v. Zimmer, Inc*., 386 F.3d 235, 244 (3d Cir. 2004). Mr. Galmines has successfully done so.

1. Novartis' off-label marketing scheme was a substantial factor in causing third parties to submit false claims to the government

Novartis asserts that Relator has not properly alleged that its off-label marketing campaign was a substantial factor in causing false claims to be submitted to federally funded healthcare programs because he has not refuted the presumption that physicians exercise "independent medical judgment when prescribing off-label." MTD at 35. Thus, it is "just as foreseeable that doctors will prescribe Elidel off-label based on their own judgment as they would based on the company's alleged off-label marketing message." *Id*. Novartis' argument is a variation of the well-refuted proposition that a Relator's allegations cannot establish the causation element in an off-label marketing case because the actions of physicians and pharmacists were an intervening force that breaks the chain of legal causation. *See Franklin v. Parke-Davis*, 147 F. Supp. 2d at *52-53 (U.S. Dist. Mass. 2001)(citing *United States ex rel.*

Cantekin v. University of Pittsburgh, 192 F.3d 402, 416 (3d Cir. Pa. 1999)). Certainly, it is a basic principle of tort law that once a defendant sets in motion a tort, the defendant is generally liable for the damages ultimately caused, unless there are intervening causes. *Id*. W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on Law of Torts § 44 (5th ed. 1984); *see also Cantekin*, 192 F.3d at 416. *However*, as explained in *Franklin*:

> …. such an intervening force **only breaks the causal connection when it is unforeseeable.** [*citing Cantekin*, 192 F.3d at 416]. *Accord* D. Dobbs, et al., Prosser and Keeton on Torts § 44, at 303-04 (5th ed. 1984) ("The courts are quite generally agreed that [foreseeable intervening forces] will not supersede the defendant's responsibility."); Restatement (Second) of Torts § 443 (1965) ("The intervention of a force which is a normal consequence of a situation created by the actor's ... conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about**."**). **In this case, when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged [off-label] scheme of fraud.**

147 F. Supp. 2d at * 52-53(emphasis supplied).

Novartis' argument that physicians *might* have exercised independent medical judgment is irreparably problematic because it fails to address the premise underpinning the entire body of allegations—that the very purpose of Novartis' off-label marketing campaign was to cause physicians to write off-label prescriptions by influencing the judgment of physicians. To this end, not only did Novartis' sales force disseminate numerous false and misleading messages regarding the safety and efficacy of Elidel while omitting the FDA's findings to the contrary (*see e.g.* Complt. ¶¶ 49, 57-59, 60-65, 72-75, 77, 82-83); it sponsored countless Continuing Medical Education seminars which were constructed around its off-label messages (Compl.¶ 121); and trained and paid high prescribing physicians to disseminate its off-label messages to other physicians (Compl.¶¶ 122-127, 129). Novartis clearly intended its marketing scheme to convince vast numbers of physicians to write the prescriptions upon which the false claims for reimbursement

from the government are premised, and it is easily foreseeable that this result is what actually occurred.

Next, Novartis incorrectly argues that a physician's "independent medical judgment" excludes information provided by drugs companies – an assertion that, simply put, ignores reality. Regarding *how* physicians get their information regarding prescription drugs, Norman Fost, M.D., an FDA consultant,[15] notably explained at the 2005 FDA hearings on the safety of Elidel that:

> [W]e know from many, many studies that 90 percent of doctors get 90 percent of their information not from journals. It comes from pharmaceutical companies. That is pretty much the source of information for doctors on drugs in general, through CME, through drug industry-sponsored CME, through sampling, through direct-to-consumer ads. Those are the three major ways.
>
> This phenomenal growth in the use of these compounds outside of what is clearly intended by the label has to be the result of pharmaceutical company efforts.

MTD, excerpt J at Tr. 315.

Moreover, even the cases that Novartis relies on reject the proposition that a physician makes decisions regarding what drugs to prescribe independent of the influence of drug companies. In *Mazur v. Merck & Co.,* 964 F.2d 1348, 1356 (3d. Cir. 1992), relied on by Novartis, the court explained that a physician's independent medical judgment is based partly on "the data supplied to him from the manufacturer." Likewise, in *Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals, LP*, 634 F.3d 1352, 1362 (11th Cir. 2011), the court stated that in making medical decisions, physicians rely partly on "published literature" and other "information available to them." Novartis does not deny that it deliberately inundated physicians with its off-label message during sales calls and at CME seminars. Based on these allegations

[15] Dr. Fost, also an M.P.H., is a Professor of Pediatrics, and Vice Chairman of the Department of Medical History and Bioethics at the University of Wisconsin.

detailing Novartis' aggressive and highly coordinated campaign to get its off-label marketing messages to physicians, it is reasonable to infer that those messages were a substantial factor in causing third parties to submit false claims to the government.

2. Relator is not obligated to refute other reasons why a physician *might* have written an off-label prescription

Without citing any authority, Novartis asserts that "the obligation to plead the causation elements requires a relator to distinguish between these two foreseeable consequences [improper marketing versus a physician's independent medical decision making presumption]." MTD at 36. This argument is incorrect. Relator is not obligated *at any point in the litigation* to refute every other possible reason a physician might have written an off-label prescription. Relators are not required to plead what they do not have to prove. *E.g., Swierkiewicz v. Sorema, N.A.,* 534 U.S. 506, 511-512 (2002)(finding it incongruous to require a plaintiff, in order to survive a motion to dismiss, to plead more facts than he may ultimately need to prove to succeed on the merits."). Ultimately, it is not Mr. Galmines' burden to prove that every physician who prescribed off-label did so because of Novartis' illegal, off-label marketing efforts. Rather, it is Mr. Galmines burden, *at trial*, to prove that physicians *probably* did so. Proving that they probably did is far different from proving that they did not; and in more prosaic parlance, such issues are known as jury questions. As Judge Easterbrook wrote in *U.S ex rel. Lusby v. Rolls-Royce Corp.:*

> [E]ven a requirement of proof beyond a reasonable doubt need not exclude all *possibility* of innocence; nor need a pleading exclude all possibility of honesty in order to give the particulars of fraud. It is enough to show, in detail, the nature of the charge, so that vague and unsubstantiated accusations of fraud do not lead to costly discovery and public obloquy. . . . To say that fraud has been *pleaded* with particularity is not to say that it has been proved (nor is proof part of the pleading requirement). [Relator's] complaint may be wrong. . . . **No complaint needs to rule out all possible defenses.**

570 F.3d 849, 854-55 (7th Cir. 2009) (italics in original; bold emphasis added; internal citations omitted). At the pleading stage in particular, Relator need only adequately allege that the Novartis' conduct was a "substantial factor" in causing false claims for Elidel to be submitted to the government. Mr. Galmines' allegations easily fulfill the substantial factor requirement; and Novartis' "alternative explanation" offers nothing whatsoever to negate that.

3. Relator has adequately alleged how Novartis' kickback scheme caused third parties to submit false claims to the government

Additionally, Novartis asserts in a single conclusory sentence that Relator has also failed to allege how kickbacks provided to physicians caused the submission of false claims based on his kickback allegations. MTD at 41-42. This argument is easily dismissed. Much in the same way that it orchestrated its national off-label campaign, Novartis implemented a systemic plan to pay kickbacks to physicians throughout the United States in order to induce them to prescribe Elidel for off-label uses. Compl. ¶¶ 2; 128, 142, 150-152. The kickbacks included gifts such as meals, bottles of wine, and pre-paid travel arrangements. Compl. ¶¶ 118-1419; 134-139. Physicians whom Novartis viewed as having "potential" to order high numbers of Elidel were provided "honoraria" in return for prescribing Elidel. Compl. ¶ 120. Physicians were selected to act as Novartis' speakers or for "preceptorships" based solely on their high volume of prescriptions. Compl. ¶¶ 123-124. These engagements however, were simply a way to funnel money to high prescribing physicians and were not based on fair market value for services. Oftentimes the speaking engagements never occurred. Compl. ¶¶ 128-131. Finally, Novartis continuation of these kickbacks to a physician was based on whether a physicians responded favorably by writing more Elidel prescriptions. Compl. ¶¶ 117, 123-124.

Together, these allegations form a seamless picture of how Novartis intended its kickbacks to cause physicians to write off-label prescriptions; and that the resulting false claims to federally funded health care programs were foreseeable.

C. Relator's allegations show that Novartis' conduct was material to the government's decision to reimburse off-label prescriptions

Novartis argues that Relator cannot show the requisite materiality under the FCA. MTD at 37. The FCA requires that Relators show that the defendant's conduct was "material", in the sense that the alleged conduct has a "natural tendency to influence or was capable of influencing the government's funding decision." *U.S. ex. rel. Thomas v. Simens AG*, 708 F.Supp 2d 505, 513 (E.D. PA 2010)(quoting *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc*., 400 F.3d 428, 446 (6th Cir. 2005); *United States ex rel. Harrison v. Westinghouse Savannah River Co*., 352 F.3d 908, 917 (4th Cir. 2003). Novartis complains that Relator must show that "at the very least" the alleged falsity was capable of influencing the resulting payment. MTD at 37.

Novartis' materiality argument misses the mark. It does not address at all the plain ambits of its contract with the United States. In order to be eligible for payment for its drugs, drug manufacturers enter into rebate agreements with the United States and subject themselves to the requirements of federal healthcare laws in return for enormous revenue from the federal healthcare system. Nor does it address that the provisions at issue are *coverage* provisions and, as such, are conditions of payment of the claim. In the rebate statute, "covered outpatient drugs" is specifically defined to exclude drugs which are "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k); ¶¶ 36-38.

Novartis' schemes to use false statements and omissions to cause the prescription of drugs which do not comport with the coverage provisions of its drug, or its contractual

commitment with the United States, is —at the very least" capable of influencing the funding decisions of the Government. Indeed, Relator alleges that the United States would not have paid the claims had it known of Novartis' fraudulent scheme. Compl., ¶ 152.

It is axiomatic that the Government only pays for claims that are covered and payable and that claims for non-reimbursable items are false claims. *Walker*, 433 F.3d at 1356 (11th Cir. 2005); *United States v. Calhoon*, 97 F.3d 518, 529 (11th Cir. 1996); *Peterson*, 508 F.2d at 52.

Moreover, courts have consistently held that the knowing submission of claims resulting from violation of a condition of payment creates False Claims Act liability. *E.g., United States ex rel. Hutcheson v. Blackstone Med. Inc.*, __ F.3d __ , 2011 U.S. App. LEXIS 10972 (1st Cir. June 1, 2011); *United States ex rel. SAIC*, 626 F.3d 1257 (D.C. Circuit 2010); *United States v. Rogan*, 459 F. Supp. 2d 692, 714 (N.D. Ill. 2006), *aff'd* 517 F.3d 449 (7th Cir. 2008);. The Third Circuit has joined these courts, by recently adopting the implied certification theory of liability which establishes FCA liability where a defendant, as here, violates conditions of payment. *United States ex rel. Wilkins v.United Health Group,* __ F.3d __, 2011 U.S. App. LEXIS 13322 (3d Cir. June 30, 2011).

In *U.S. ex rel. Kirk v. Schindler-Elevator Corp*., 601 F.3d 94, 117 (2d Cir. 2010), *rev'd* and *remanded* on other grounds, __ U.S. __ 131 S. Ct. 1885 (May 16, 2011), the Second Circuit held that the false reporting on annual reports required to be filed with the government gave rise to liability because it was capable of influencing the payment of claims. In evaluating materiality, the Second Circuit held that the fact that the annual reports were —sufficiently important to Congress that it made fulfillment of them a precondition of payment" satisfied the § 3729 (a)(1)(B) standard. Here, Mr. Galmines has set forth in the allegations the FDA prohibition on off- label marketing, Compl. ¶¶ 13-17; and the statutory preconditions that limit federal health

programs' payments for prescription drugs that are the result of, or were influenced by, off-label marketing. Compl. ¶¶ 23-24; 33; 146-149. As in *Kirk*, here the coverage restrictions for off-label uses are "sufficiently important to Congress" such that Congress not only mandated that federal healthcare agencies not pay for off-label uses, but also mandated that pharmaceutical companies may not market or promote prescription drugs for off-label uses.

Moreover, in *U.S. ex rel. Franklin v. Parke-Davis,* the defendant made an identical argument to Novartis' that false statements made by defendant's sales representatives to doctors were not material to the government's decision to pay claims for off-label prescriptions. The district court fully rejected this argument explaining that:

> Liability under the FCA, however, is not limited only to false statement or claims made directly by the Defendant to the government. The Act "reached beyond claims which might be legally enforced, to all fraudulent attempts to cause the Government to pay out money." *Neifert-White Co*., 390 U.S. at 233 (internal quotations omitted)…**The fact that such prescriptions are for an off-label use, is material because … the government would not have paid the claims if it had known of the use for which they were being submitted**.

147 F. Supp. 2d 39, * 53 (D. Mass. 2001) (emphasis supplied).

Novartis however, attempts to refute the clear materiality of its messages by pointing out that exceptions to the general prohibition on reimbursement for off-label prescriptions exist for off-label prescriptions that fit certain criteria evidencing medical necessity, such as: being covered in a recognized compendia; supported by medical literature; recognized by a national organization; or supported by "accepted standards of medical practice." MTD at 38-39. But the simple fact --which is entirely undisputed by Novartis -- is that *none* of these exceptions apply here. None of the enumerated compendia supports off-label uses of Elidel for the purposes Novartis marketed it for. Novartis cites to no medical literature supporting use of Elidel for off-label purposes that show that it is safe and effective in contradiction to the FDA's findings. Novartis points to no national organization lauding the off-label use of Elidel; and it cites to no

accepted authority supporting the off-label use of Elidel for any of the off-label uses that Novartis marketed it for. Novartis has failed entirely to address the critical allegation set forth in the Complaint: that the government has stated in no uncertain terms that it will not pay for off-label claims resulting from illegal off-label marketing. Therefore, the fact that an off-label prescription *could* be legally reimbursed if it fit specific criteria is a *non sequitur* in this litigation, and should be ignored.[16]

Indeed, it is simply not credible for Novartis to assert that it does not understand its exposure under the False Claims Act for off-label marketing and payment of kickbacks, since it has admitted to off-label marketing of its pharmaceutical products before this very Court. In September 2010, Novartis was convicted on a plea of guilty to a misdemeanor count of misbranding the drug Trileptal by marketing it for off-label uses. In the plea agreement, which is summarized in the Government's Memorandum for Entry of Plea and Sentencing (Exhibit 9), Novartis admitted to "promote[ing] Trileptal as treatment for bipolar disorder and neuropathic pain" in violation of 21 U.S.C. § 352(f)(1). Novartis paid criminal fines and forfeitures of $185,000,000 on its guilty plea. The criminal conduct occurred in 2000 and 2001, precisely the period of time that it was ramping up Mr. Galmines and his colleagues to market Elidel for infant use.[17]

[16] In response to footnote 28 of the MTD, while the Oklahoma Medicaid program has approved off-label use for children under two in limited circumstances; the fact remains that there is no exception to pay for off-label use if the prescription is the result of a pharmaceutical's illegal off-label campaign or induced by kickbacks, as alleged here.

[17] Also in September 2010, Novartis entered into a civil settlement with the United States and several *qui tam* relators, pursuant to which it paid False Claims Act damages of $237,500,000 for off-label marketing and payment of kickbacks with respect to Trileptal and several other drugs (Diovan, Zelnorm, Sandostatin, Exforge and Tekturna).

D. Relator's kickback allegations state a claim under the FCA

Novartis argues that Mr. Galmines has failed to state an FCA claim based on Anti-Kickback Statute ("AKS") violations based on its view that the FCA requires that kickback allegations be based on either a facial falsity, an "express" certification of compliance with the AKS, or an "implied" certification based on an *express statement* in the statute itself that compliance is a condition of payment. MTD at 40-41. Novartis' resuscitation of the legal standard is simply in error.

The majority of circuits have found that FCA liability is established when defendants knowingly submit or cause the submission of false claims in violation of material conditions of payment, whether or not the claim is facially false or an express certification of compliance accompanies the claim. *E.g., United States ex rel. Hutcheson*, 2011 U.S. App. LEXIS 10972; *SAIC*, 626 F.3d 1257; *Rogan*, 459 F. Supp. 2d at 714, *aff'd* 517 F.3d 449; *United States ex rel. McNutt v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005); *see also United States ex rel. Fry v. Health Alliance*, 2008 U.S. Dist. LEXIS 102411 (S.D. Ohio December 18, 2008); *United States ex rel. Pogue v. DTCA (Pogue III)*, 565 F. Supp. 2d 153, 158-159 (D.D.C. 2008).

Courts have called this method of establishing falsity "implied certification," based on a long line of cases concluding that withholding information critical to the decision to pay is "the essence of a false claim." *Ab-Tech Const. Inc. ,v. United States*, 31 Fed. Cl. 429 (Fed. Cl. 1994). In two recent decisions, the First Circuit and the D.C. Circuit declined to narrowly employ terms like" implied certification," finding that employing terms found nowhere in the statute may "obscure rather than clarify the issues." *Hutcheson,* 2011 U.S. App. LEXIS at *23. Going back to the text of the FCA, the First Circuit and D.C. Circuits found that the concepts of knowledge and materiality properly cabined liability within the intent of the statute. *Hutcheson* at *31; *SAIC*

at 1270. Plainly speaking, FCA liability arises when a defendant knowingly causes the submission of a material condition of payment. As the D.C Circuit observed, notwithstanding how each court captions the liability theory, courts have not rejected FCA claims where —the defendant sought payment after knowingly violating a material requirement of its contract." *SAIC,* 626 F.3d. at 30.

Whether called —implied certification" or —condition of payment," the analysis focuses on whether the conduct at issue establishes the falsity of the resulting claim. While the Third Circuit previously had not decided whether it adopted an implied certification theory of liability, its recent decision in *United States ex rel. Wilkins* expressly adopts the theory and defines this approach consistent with the decisions of many of its sister Circuits. 2011 U.S. App. LEXIS 13322. The *Wilkins* court made clear that its decision to adopt implied certification as a theory of liability was intended to —give effect to Congress' expressly stated purpose that the FCA should reach all fraudulent attempts to cause the Government to pay [out] sums of money or to deliver property or services.'" *Id.* at *26, *quoting* S. Rep. No. 99-345, at 9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274. Finding the theory of liability consistent with the —language and structure of the FCA," the Third Circuit specifically identified that its ruling effectuates Congress' stated intent that:

> [A] false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation . . . . [Claims made to Medicare or Medicaid programs] may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program. . . .

Id. at *26-27, *quoting* S. Rep. No. 99-345, at 9, reprinted in 1986 U.S.C.C.A.N. 5266, 5274.

Thus, the Third Circuit held, a plaintiff properly states a cause of action under the FCA when defendant has violated statute or regulation which is a —condition of payment from the

Government." *Wilkins,* at *33.

1. The Third Circuit has concluded that compliance with the AKS is a condition of payment of federal healthcare programs

The Third Circuit found that compliance with the AKS is a condition of payment of federal healthcare programs. It specifically held that, by alleging that defendants "violated the AKS while submitting claims for payment to a federal health insurance program," as Mr. Galmines does in his Complaint, plaintiffs "have stated a plausible claim for relief under the FCA." *Wilkins* at *50.

The Third Circuit did not require, as Novartis would have it, that the AKS must explicitly contain language stating that compliance with its provisions are a "condition of payment" (which would certainly be difficult, given that this phrase was judicially-created long after the enactment of the AKS[18]). Rather, the Third Circuit recognized long-standing precedent, holding that compliance with the AKS is a condition of payment under federal health insurance programs, as well as the fact that the AKS is a statute that is "designed to prevent or ameliorate fraud, waste, and abuse." *Wilkins* at *48 (quoting 42 C.F.R. §§ 422.504(h), 423.505(h)). Rejecting defendants' arguments that this creates "strict liability" for AKS violations, the Third Circuit explained:

> Compliance [with the AKS]…does require a participant in a federal health care program to refrain from offering or entering into payment arrangements which violate the AKS, while making claims for payment to the Government under that program. We do not think this is an unreasonable requirement to impose on federal health care contractors, for as Justice Holmes once wrote: "Men must turn square corners when they deal with the Government." Rock Island, A. & L. R.

[18] While no "magic words" are be required to establish that the compliance with AKS is a condition of payment of claims, recent amendments to the AKS resolve any possible ambiguity. Passed in response to judicial decisions limiting the scope of FCA cases premised on AKS allegations, the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No.111-148, § 6402(f)(1), amends the AKS to squarely clarify that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." Add. at 41, PPACA § 6402(f); codified at 42 U.S.C. 1320a-7b(g).

> Co. v. United States, 254 U.S. 141, 143, 41 S.Ct. 55, 56 (1920). And as the United States as amicus curiae points out, "[t]he Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback."

Wilkins at *50-51.

The Third Circuit's analysis focused on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment.'" *Wilkins* at *46 (quoting *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.,* 543 F.3d 1211, 1218 (10th Cir. 2008)). This inquiry, unlike the "magic words" analysis employed by defendants, is essentially an analysis of whether the violation at issue was material to the claim. *United States ex rel. Lemmon v. Envirocare of Utah, Inc.,* 614 F.3d 1163, 1168-69 (10th Cir. 2010).

The Third Circuit's conclusion is amply supported here, where Relator alleges that Novartis knowingly caused the submission of claims to Medicare and Medicaid by systemic payment of kickbacks to physicians to write off-label prescriptions.

As the Complaint states, *all* participants in the federal healthcare system are required to comply with the AKS, which expressly prohibits conduct which results in false claims.[19] Compl. ¶¶ 18-22. The AKS specifically prohibits the payment of kickbacks, directly or indirectly, in cash or in kind, in return for the referral, purchase, arranging or recommending of "anyitem or service **for which payment may be made in whole or in part by a Federal health care program**." 42 U.S.C. 1320a-7b(b)(emphasis added). Compl. ¶ 18. In addition to the citations by the *Wilkins* court, the legislative record is replete with evidence that the purpose of the AKS

[19] Mr. Galmines alleges not only that that the each of the federally-funded healthcare programs require compliance with the AKS in order to seek payment (Compl., ¶20), but also that the United States would not have paid the resulting claims had it known the claims to be the result of the illegal schemes alleged in the Complaint. *Id.,* ¶ 152.

was designed to attack the fraud, waste and abuse caused by kickback schemes, and wholly prevent claims tainted by kickbacks from being paid by federal healthcare programs. Indeed, the AKS proscriptions were premised on the overwhelming findings that kickbacks are directly related to intolerable increases in federal healthcare claims.[20] In 1977, The Senate called for felony provisions to be added to the AKS, specifically recommending that "the Department of Justice should intensify its efforts to identify ***[M]edicare and [M]edicaid fraud*** and to recover federal funds inappropriately paid out under these programs."[21] As said by one of the 1977 amendment sponsors: The anti-kickback laws were introduced to "give a clear, loud signal to the thieves and the crooks and the abusers that we mean to call a halt to their exploitation of the public and the public purse."[22] Again and again, Congress has called out kickbacks as a root cause of fraud and waste of federal programs and armed the AKS as a means of barring those fraudulent claims.[23]

The statute and legislative record make plain that compliance with the AKS is a condition of payment for all federal programs. Moreover, the Department of Health and Human Services ("HHS"), the agency charged with implementing the statute, has consistently targeted kickbacks as a significant source of fraud on Medicare and Medicaid programs. As stated in the *Final Compliance Program Guidance for Pharmaceutical Manufacturers*,

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[20] *E.g.*, S. Rep. 95-320, Kickbacks Among Medicaid Providers, A Report of the Special Committee on Aging, 95th Cong., 1st Sess. at 2 (June 30, 1977) (1972 law is "plea for aggressive action to root out fraud and abuse."); *see also* 123 Cong. Rec. 31767 (September 30, 1977) (Remarks of Sen. Talmadge).

[21] *Id.* at 29.

[22] 123 Cong. Rec. 31767 (September 30, 1977) (Remarks of Sen. Talmadge).

[23] H. Rep. 95-393, 95th Cong., 1st Sess. at 44, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3047; S. Rep. 100-109, 100th Cong., 1st Sess. at 1 *reprinted in* 1987 U.S.C.C.A.N. 682, 682.

> Manufacturers, providers, and suppliers of health care products and services frequently cultivate relationships with physicians in a position to generate business for them through a variety of practices, including gifts, entertainment, and personal services compensation arrangements. These activities have a high potential for fraud and abuse and, historically, have generated a substantial number of anti-kickback convictions. There is no substantive difference between remuneration from a pharmaceutical manufacturer or from a durable medical equipment or other supplier—if the remuneration is intended to generate any federal health care business, it potentially violates the anti-kickback statute.

68 Fed. Reg. 23731, 23737 (May 5, 2003). The Agency specifically warned pharmaceutical companies, and other manufacturers, providers, and suppliers, that their AKS violations bring with it not just criminal implications, but potential exclusion from participation in the system, and FCA liability. *E.g.*, 68 Fed. Reg. 23731, 23734 & 23737 (May 5, 2003).[24]

The statutory language and body of authority clearly support that compliance with the AKS is, as a matter of law, material to, and a condition of, claims for payment under federally-funded healthcare programs. Thus, Mr. Galmines' allegations sufficiently state a claim based on Novartis' kickbacks to physicians.

[24] Special Fraud Alert, *Joint Venture Arrangements*, *reprinted at* 59 Fed. Reg. 65372 (December 19, 1994). It can also be found at http://oig.hhs.gov/fraud/fraudalerts.asp.; Special Advisory Bulletin, *Contractual Joint Ventures,* April 2003, http://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf; Letter and Guidance, Oct. 6, 2006, *Physician Investments in Medical Device Manufacturers and Distributors,* http://oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20%282%29.pdf. By way of further example, the agreement signed by every provider in the Medicare system states, "I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare." https://www.cms.gov/cmsforms/downloads/cms855i.pdf .

E. Relator adequately alleges a conspiracy between Novartis and several particular physicians

The False Claims Act holds liable those who conspire to commit an act that violated the FCA . A conspiracy claim must adequately plead (1) a conspiracy to get a false or fraudulent claim allowed or paid; and (2) an act in furtherance of the conspiracy." *United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir. Pa. 2007); *U.S. ex rel. Sanders v. Am-Amicable Life Ins. Co. of Texas*, No. 03-4327, 2007 WL 2032914, at *4 (E.D. PA July 12, 2007, *aff'd* 545 F.3d256 (3d Cir. 2008). Furthermore, a conspiracy hinges on —an agreement between two or more people to commit fraud." *U.S. ex rel. Bartlett v. Tyrone Hosp., Inc*., 2134 F.R.D. 113, 124 (W.D. PA. 2006).

Novartis argues that Relator has failed to allege a conspiracy because he has not included any details regarding agreements with doctors to defraud the government by submitting false claims; thus Relator has not showed a —meeting of the minds" between Novartis and doctors who were paid kickbacks. MTD at 42. This is not true. Relator has included details regarding the specific agreements between Novartis and several individual physicians who agreed to write Elidel prescriptions and help to disseminate Novartis' off-label message for kickbacks.

By way of example, Relator was instructed by his manager to provide Dr. Dolar Koya kickbacks in the form of a trip to France. Dr. Koya accepted, acknowledging that in exchange for the trip, he would write Elidel prescriptions by stating: —[m]y patients will use whatever I tell them to. I know how the system works- you take care of me and I will take care of you." Compl. ¶ 119. Similarly, Relator paid money for a —preceptorship" to Dr. David Coynik for prescribing Elidel. Reflecting his agreement to receive kickbacks in exchange for writing Elidel prescriptions, Dr. Coynik states —as long as you pay me, I'll prescribe Elidel by the truckload." Compl. ¶ 141.

Furthermore, Novartis routinely paid physician speakers (of which there were at least 700) specifically to promote Elidel's off-label message and were expected to include slides with off-label messages and lead discussion on off-label uses in order to receive payment. Compl. ¶¶ 121-122, 129.

IV. RELATOR'S ALLEGATIONS MORE THAN SATISFY RULE 9(b)'s PARTICULARITY REQUIREMENT

The purpose of Rule 9(b)'s heightened pleading standard is "to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984). While the Third Circuit appears to require that Rule 9(b)'s heightened standard applies to FCA Complaints, "it has not yet defined that standard." *Underwood,* 720 F. Supp.2d at 676 (citing *U.S. ex rel St. John LaCorte v. Smithkline Beecham Clinical Lab*., 149 F.3d 227, 234 (3d Cir. 1998)). The Third Circuit, however, has and specifically cautioned against overemphasizing Rule 9(b)'s specificity requirement:

> [U]nder Fed. R. Civ. P. 9(b), plaintiffs must plead with particularity the "circumstances" of the alleged fraud. They need not, however, plead the "date, place or time" of the fraud, so long as they use an "alternative means of injecting precision and some measure of substantiation into their allegations of fraud.

Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658 (3d Cir. 1998), *abrogated on other grounds by Rotella v. Wood*, 528 U.S. 549 (2000) (quoting *Seville Indus. Mach. Corp.*, 742 F.2d at 791); *United States ex rel. Thomas v. Siemens AG*, 708 F. Supp. 2d 505, 511 (same). As discussed below, Mr. Galmines' allegations contain sufficient precision to place Novartis on notice of the conduct for which it is liable.

A. Relator is not required to identify a specific claim in order to satisfy Rule 9(b)

Novartis relies on outdated, non-binding authority in urging the Court to dismiss Mr. Galmines' complaint under Rule 9(b). MTD at 32-33. Novartis' primary support comes from the 2001 Eleventh Circuit decision *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301. In the ten years since *Clausen*, however, a series of well-reasoned circuit and district court opinions—including a recent decision issued by Judge Diamond in this District—have rejected the Eleventh Circuit's overly-strict application of Rule 9(b) in pleading claims brought pursuant to the False Claims Act. These cases, rather than erecting an almost impenetrable barrier to nearly every category of Relator—regardless of the significance of their knowledge of the defendant's unlawful conduct—by requiring proof of specific claims filed with the government, instead hold that a relator can satisfy the heightened pleading requirements by including allegations that are sufficiently detailed to permit an inference that claims were in fact submitted. *E.g., Lemmon,* 614 F.3d at 1171-72 ("[C]laims under the FCA need only sow the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme"); *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (a complaint which does not allege "details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted"); *U.S. ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) (Easterbrook, C.J.)(in reversing a Rule 9(b) dismissal, observed that "much knowledge is inferential…."); *accord U.S. ex rel. Ebeid v. Lungwitz*, 616 F.3d 993, 998-1000 (9th Cir. 2010 (adopting the "reliable indicia" standard of *Grubbs*); *U.S. ex rel. Resnick v. Weill Medical College of Cornell University*, No. 04-C3088, 2010 U.S. Dist. LEXIS 11019, at *12 (S.D.N.Y. Jan. 21, 2010) (same); *U.S. ex rel.*

Folliard v. CDW Tech. Servs., 722 F. Supp. 2d 20, 27 (D.D.C. 2010) (noting the distinction between the circumstances of the fraud, which must be pled with specificity, and the existence of the claim for payment, which may be pled generally).

Notably, several recent cases involving the off-label promotion of prescription drugs have survived Rule 9(b) scrutiny despite the absence of allegations of specific false claims. *E.g., U.S. ex rel. Duxbury v. Ortho Biotech Prods., Inc*., 579 F.3d 13, 29-30 (1st Cir. 2009), *cert. denied*, 130 S. Ct. 3454 (2010) (quoting *Rost*, 57 F.3d at 733) (holding that a relator can ~~sa~~tisfy Rule 9(b) by providing ~~"~~factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim."); *U.S. ex rel. Strom v. Scios, Inc*., 676 F. Supp. 2d 884, 893 (N.D. Cal. 2009)(rejecting a *Clausen*-based argument against a complaint alleging off-label marketing of a prescription drug).

The weight of authority has shifted away from the iron-clad interpretation of Rule 9(b)'s pleading standard and toward a more reasoned approach that properly balances the rights of defendants to receive notification of the allegations levied against them and the reality that even the most knowledgeable relator should not be expected to prove her case by a preponderance of the evidence before discovery has even begun. *See Lusby*, 570 F.3d at 855 (~~"~~To say that fraud has been *pleaded* with particularity is not to say that it has been *proved* (nor is proof part of the pleading requirement).") (emphasis original). Mr. Galmines has provided ample detail to support his allegations.

1. In *Underwood*, this district court rejected the argument that a relator must identify a specific claim in order to satisfy Rule 9(b)

On June 2, 2010, Judge Diamond of this District issued a decision in *U.S. ex rel. Underwood v. Genentech, Inc.,* 720 F. Supp. 2d 671 (E.D. Pa. June 2, 2010,), rejecting the defendant's argument that the relator must plead specific claims to satisfy Rule 9(b)'s pleading

requirement. *Underwood's* allegations bear substantial similarities to Mr. Galmines', and the Court's analysis in that case is directly applicable to the issues raised by Novartis. Mr. Underwood, the relator, was a sales manager for Defendant Genentech, a manufacturer of the FDA approved drug Rituxan. *Id*. at 673. Underwood alleged that Genentech engaged in a long term off-label marketing and kickback scheme, which resulted in the submission of numerous fraudulent reimbursement claims to Medicare and Medicaid. *Id.* In concluding that it is not always necessary for a relator to plead a specific claim, Judge Diamond aptly noted that where a defendant induces third parties (such as physicians or pharmacists) to submit false claims to the government, it is unreasonable to require the relator to identify at the pleading stage a specific false claim submitted to the government by a third party:

> requiring production of actual documentation with the complaint [would require] a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." *Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009.) Indeed, requiring every relator alleging the indirect submission of fraudulent claims to identify in his complaint a specific false claim would effectively eliminate part of the False Claims Act. See 31 U.S.C. § 3729(a)(1) (any person who "presents, or causes to be presented, a false or fraudulent claim for payment . . ., is liable to the United States government for a civil penalty") (emphasis supplied).

Id. at 679 (distinguishing the fact from the *Clausen* line of cases in which defendant companies had submitted false claims directly to the government.)[25] Mr. Galmines has similarly alleged that through its off-label marketing campaign, Novartis induced physicians to write non-covered prescriptions that were submitted through pharmacies to federally funded health care programs, and Novartis readily admits that it did not submit claims for reimbursement itself. Compl. ¶ 32

[25] This view is supported by *U.S. ex rel. Lusby v. Rolls-Royce Corp*., 570 F.3d 849 (7th Cir. 2009)(noting that "a relator is unlikely to have [billing] documents unless he works in the defendant's accounting department," thus the *Clausen* principle "takes a big bite out of *qui tam* litigation").

n.19. Like Mr. Underwood, Mr. Galmines had no access to specific claims information. Thus to require him to plead specific claims with specificity would not only be impractical, but also would undermine one of the central purposes of the False Claims Act: to hold accountable defendants *who cause others* to submit false claims.

B. Relator's allegations answer the traditional reporter's questions

One means of "injecting precision" into false claims allegations is to answer the "traditional reporter's questions" including the "who, what, when, where and how of the events of the issue." *In re Rockefeller Ctr. Properties*, *Inc. Sec. Litig*., 311 F.3d 198, 217 (3d Cir. 2002), *overruled in part on other grounds by Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554-55 (2007). The Court in *Underwood* held that the relator had successfully injected enough precision in his allegations to meet Rule 9(b)'s particularity requirement based *solely* on the level of detail the relator included in his complaint:

> [Relator] has set out Genentech's alleged actions from 2000 through "at least December 2002" to bribe doctors and other health care providers to write thousands of Rituxan prescriptions for non-approved uses. He has described the kinds of bribes in some detail. He has alleged that many thousands of prescriptions were written for Medicare/Medicaid patients, resulting in the presentation of many millions of dollars in false claims to the Government. (Doc. No. 15 at PP 23-34.) There is no mystery or ambiguity to these allegations. Either Genentech lavishly bribed doctors to prescribe Rituxan for off-label use or it did not. Relator's allegations are sufficiently specific both to inform Genentech of the "precise misconduct" charged, and to make it unlikely that Relator has commenced this action in bad faith.

Id. at 680.

The Underwood Court's analysis of the relator's allegations appears to employ a traditional reporter's question analysis, accepted by the Third Circuit. *In re Rockefeller Ctr. Properties,* 311 F.3d at 217. Other courts have held in FCA cases that particularity is met where the relator has alleged information answering the "traditional reporter's questions" of "who,

what, when, where, and how" of the fraud. *E.g., Lusby* 570 F.3d at 853; *U.S. ex rel. Wood v. Applied Research Ass'n., Inc*., 328 F. App'x 744 (2d Cir. 2009), *cert. denied*, 130 S. Ct. 1285 (2010) ("[To satisfy] the pleading requirements of Rule 9(b), … a complaint must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent."); *Duxbury,* 579 F.3d 29-30 ("Although Duxbury does not identify specific claims, he has alleged the submission of false claims across a large cross-section of providers that alleges the who, what, where, and when of the allegedly false or fraudulent representation").

Turning to the case at bar, Mr. Galmines' allegations contain more than enough detail to answer the "who, what, where, when, and how" of Novartis' off-label and kickbacks schemes:

Who: Novartis, via its marketing teams, national sales trainers, and management.

What: To increase its profits, Novartis unlawfully marketed Elidel to physicians and directly to the public by intentionally misrepresenting the FDA limitations on the label, causing millions of prescription for unapproved ("off-label") uses to be written and reimbursed by federally funded health care programs. Novartis' marketing team created and standardized a set of core programs and material containing off-label messages which were disseminated through its sales force. Novartis sales representatives were trained to promote off-label use of Elidel by misleading physicians about the safety of its product for infants, chronic, and first line treatment and Novartis also trained and paid physicians to disseminate its off-label message to other physicians. Compl. ¶¶ 2, 54, 56, 57, 58, 59, 65, 67, 71, 88, 91,92, 95.

In conjunction with its off-label marketing scheme, Novartis implemented a systemic plan to pay kickbacks to health care providers across the nation to induce off-label Elidel prescriptions. Compl. ¶¶ 2; 128, 142, 150-152.

Where: Novartis directed its off-label messages to both physicians and to the public. Novartis directed its sales force to disseminate its off-label messages directly to physicians in their offices and at Continuing Medical Education seminars. Compl. ¶¶ 69; 79, 91, 121, 122. It also advertised these off-label messages on its public website. Compl. ¶¶ 73; 74 . 99-100.

Regarding kickbacks, Novartis especially targeted high- prescribing doctors for kickbacks. Compl. ¶¶ 117, 120, 123-125 , 132, 133, 135-139; 141. Relator specifies numerous incidences of specific kickbacks paid to individually names physicians in a variety of setting such at restaurants and seminars. Compl. ¶¶ 119, 126, 131, 129

When: Novartis began its off-label marketing campaign and kickback scheme for Elidel beginning in approximately 2002 and continues despite the addition of the FDA black box warning. Compl. ¶¶ 11, 99-100.

***How*:** Novartis used myriad methods to disseminate its off-label messages. These include, *inter alia*, the following messages:

- Visual aids promoting off-label use used by sales representatives when calling on physicians. Compl. ¶ 76;
- False statements regarding the safety of Elidel for infants based on the inclusion of the infant study data in the label. Compl. ¶¶ 58-59; 65; 67;
- False statements regarding the safety of Elidel compared to competitor products containing steroids. Compl. ¶¶ 49; 57; 78, 99;
- Misleading statements that Elidel was safe because of negligible blood serum levels, when Elidel is absorbed through the lymphatic system and not the blood system. Compl. ¶¶ 68; 88;

- Novartis sponsored Eichenfield and Kapp scientific studies promoting off-label use of Elidel, omitting all information of FDA determined risks. Promoted in a variety of formats, through reprints, press releases, detail pieces directly to physicians during office calls, at CMEs. Compl. ¶¶ 60-64; 72-75; 82-85, 88; and

- Misleading statement in Novartis' direct to public marketing through website: Compl. ¶¶ 73-74; 99-100.

Novartis also used a variety of kickbacks to induce physicians to write prescriptions for Elidel. These included gifts such as meals, bottles of wine, and pre-paid travel arrangements. Compl. ¶¶ 118-119; 134-139. Physicians that Novartis viewed as having the potential to order high numbers of Elidel were provided honoraria in return for prescribing Elidel. Compl. ¶ 120. Based solely on their high volume of prescriptions, physicians were selected to act as Novartis' speakers or for "preceptorships". Compl. ¶¶ 123-124.

Additionally, Mr. Galmines' complaint also satisfies Rule 9(b) because he has set forth factual and statistical evidence from which it can reasonably be inferred that false claims for off-label uses were actually submitted due to Novartis' off-label campaign and kickback scheme. *See e.g. Grubbs*, 565 F.3d at 190 (requiring particular details of a scheme plus "reliable indicia" that claims were actually submitted*); Duxbury*, 579 F.3d at 20-20. Most compelling is Novartis' own statement that 20% of Elidel sales were from prescriptions for infants under two years of age. Compl. ¶ 116. The FDA also attributed at least 14% (or 1.2 million prescriptions for Elidel between 2001-2004) to prescriptions written for infants under two years of age. Compl. ¶¶ 104-107. These figures are congruent with Novartis' statements by its national sales trainer that the most successful sales representatives were selling Elidel for off-label infant use. Compl. ¶ 87; and Novartis' CFO's statement attributing Elidel' s success to its marketing campaign. Compl. ¶ 93. Likewise, Novartis knew that its kickback scheme was successful because it tracked the prescribing habits of physicians and rewarded high volume prescribers with cash

payment and gifts. Compl. ¶¶ 117, 123-124; 132. Together, these details provide an overpowering basis for reasonable inference that false claims were submitted as part of the off-label marketing and kickback schemes.

Finally, should the Court conclude that, despite the factual detail supplied by Mr. Galmines and the strength of the inference that Novartis' conduct led to the submission of false claims, insufficient detail has been pled to satisfy the requirement of Rule 9(b), Relator respectfully asks that the Court grant an opportunity to amend the complaint. As this Court has previously observed, "[t]he Court should freely give leave when justice so requires." *Harrison v. SEPTA*, Civil Action No. 07-4174, 2008 U.S. Dist. LEXIS 97332, at*5 (E.D. Pa. Dec. 1, 2008). Thus, "[i]n the absence of substantial or undue prejudice to the nonmoving party, denial of leave to amend "must be based on bad faith or dilatory motives, truly undue or unexplained delay, repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment." *Id.* at *5-6 (internal citations omitted); *Amerisourcebergen Drug Corp. v. Kohll's Pharm. & Homecare, Inc*., Civil Action No. 09-1166, 2010 U.S. Dist. LEXIS 102736, at *6 (E.D. Pa. Sept. 24, 2010) (―[T]he risk of submitting insufficient pleadings encourages prudent parties and professionals to proceed cautiously in seeking amendments, and warrants a court's indulgence of any party moving for leave to amend[.]"). The Court also has recognized that a plaintiff facing dismissal pursuant to Rule 12(b)(6) should be permitted to cure her pleading unless it is clear that amendment would be inequitable or futile. *Hobson v. St. Luke's Hosp. & Health Network*, 735 F. Supp. 2d 206, 209 (E.D. Pa. 2010). Here, Relator has not previously sought to amend, and other than the jurisdictional issues set out above, does not anticipate that amendment will be necessary. However, in the event the Court finds flaws in the factual basis

for the claims alleged, Relator urges that the Court should exercise its discretion in favor of allowing an amendment.

V. RELATOR'S STATE LAW CLAIMS

Federal law requires this Court to exercise supplemental jurisdiction over Mr. Galmines' claims alleging violations of various state false claims acts. Novartis effectively (in its failure to even to cite 28 U.S.C. § 1367) asks the Court to ignore the supplemental jurisdiction statue and dismiss Mr. Galmines' state claims.[26] With the specific exceptions discussed below, Novartis' motion to dismiss these claims should be denied.

A. The court should properly exercise supplemental jurisdiction over the California, District of Columbia, Indiana, Louisiana, Massachusetts, and Virginia claims

Pursuant to 28 U.S.C. § 1367(a) and (c), a district court —shall have supplemental jurisdiction over all other claim that are so related to claims in the action with such original jurisdiction that they form part of the same case or controversy," unless the claim: (1) —raises a novel (1) the claim raises a novel or complex issue of State law," (2) —substantially predominates over the claim or claims over which the district court has original jurisdiction," (3) —the district court has dismissed all claims over which it has original jurisdiction," or (4) —in exceptional circumstances, there are other compelling reasons for declining jurisdiction." As to Mr. Galmines' claims brought under California, District of Columbia, Louisiana, and Massachusetts law, the allegations are essentially the same as those claims brought under the federal FCA, and thus collectively form part of the same case. Moreover, none of the § 1367(c) exceptions applies. As such, supplemental jurisdiction over these claims is proper.

[26] While the case was still under seal, Mr. Galmines voluntarily dismissed the Texas and Florida state claims on May 18, 2009. Therefore, Defendant's arguments as to these two states' claims are moot.

Novartis' argument that the Indiana and Virginia state claims should be dismissed because these statutes were enacted after Mr. Galmines had filed his Complaint forms no basis to dismiss these claims. Instead, this is an argument to limit damages that should be determined at a later time.

B. Relator agrees to dismiss state claims for New Hampshire, Delaware, and New Mexico

Mr. Galmines agrees to dismiss the state claims in New Hampshire because the statute requires dismissal of claims where the state has not intervened. Likewise, Relator agrees to dismiss the Delaware and New Mexico State claims because the statutes require that state officials must make a determination whether there is substantial evidence of state FCA violation, which has not occurred.

CONCLUSION

Novartis has come at this matter with every move in the *qui tam* defendant's playbook. But this much is clear: The United States paid a substantial amount to this defendant for prescriptions which were not just off-label, but which put the health of infants in jeopardy. No prior relator has brought credible allegations, and Mr. Galmines brings claims on his own experience; so the Court has jurisdiction. The cause of action is well-recognized, and the conduct Mr. Galmines alleges fits its elements neatly. Novartis cannot possibly claim that it does not understand the allegations against it, and in fact Mr. Galmines has provided ample basis from which to find a reasonable inference that the False Claims Act was roundly violated by this defendant's conduct—and that this case is an appropriate vehicle for the United States to recover the fruits of Novartis' illegal conduct.

The motion to dismiss should be denied in all particulars, with the exception of the claims brought under New Hampshire, Delaware, and New Mexico state law.

Dated: July 1, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day a true copy of Relator Donald Galmines' Memorandum in Opposition to Defendant Novartis Pharmaceuticals Corporation's Motion to Dismiss, and exhibits, were served upon the following counsel via electronic mail:

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